



3 1761 11850076 8

A20N

Z1

-83H021



Ontario

87

MIRKIN

ROYAL COMMISSION OF INQUIRY INTO CERTAIN
DEATHS AT THE HOSPITAL FOR SICK CHILDREN AND
RELATED MATTERS.

In Ch. (P.M.C.)

Hearing held
8th floor
180 Dundas Street West
Toronto, Ontario

The Honourable Mr. Justice S.G.M. Grange

Commissioner

P.S.A. Lamek, Q.C.

Counsel

E.A. Cronk

Associate Counsel

Thomas Millar

Administrator

Transcript of evidence
for

10 JANUARY 1984

VOLUME 87

OFFICIAL COURT REPORTERS

Angus, Stonehouse & Co. Ltd.,
14 Carlton Street, 7th Floor,
Toronto, Ontario M5B 1J2

595-1065



ROYAL COMMISSION OF INQUIRY INTO CERTAIN
DEATHS AT THE HOSPITAL FOR SICK CHILDREN
AND RELATED MATTERS.

Hearing held on the 8th Floor,
180 Dundas Street West, Toronto,
Ontario, on Tuesday, the 10th
day of January 1984.

THE HONOURABLE MR. JUSTICE S.G.M. GRANGE - Commissioner
THOMAS MILLAR - Administrator
MURRAY R. ELLIOT - Registrar

APPEARANCES:

| | |
|----------------------|--------------------------------|
| P.S.A. LAMEK, Q.C.) | Commission Counsel |
| E. CRONK) | |
| D. HUNT) | Counsel for the Attorney |
| L. CECCHETTO) | General and Solicitor General |
| | of Ontario (Crown Attorneys |
| | and Coroner's Office) |
| I. J. ROLAND) | Counsel for The Hospital for |
| M. THOMSON) | Sick Children |
| R. BATTY) | |
| D. YOUNG | Counsel for The Metropolitan |
| | Toronto Police |
| K. CHOWN | Counsel for numerous Doctors |
| | at The Hospital for Sick |
| | Children |
| E. McINTYRE | Counsel for the Registered |
| | Nurses' Association of Ontario |
| | and 35 Registered Nurses at |
| | The Hospital for Sick Children |
| D. BROWN | Counsel for Susan Nelles - |
| | Nurse |
| E. FORSTER | Counsel for Phyllis Trayner - |
| | Nurse |

(Cont'd)...



Digitized by the Internet Archive
in 2023 with funding from
University of Toronto

<https://archive.org/details/31761118500768>



1 APPEARANCES (Cont'd.):

2 J.A. OLAH Counsel for Janet Brownless -
3 Nurse
4 B. KNAZAN Counsel for Mrs. M. Christie -
5 R.N.A.
6 S. LABOW Counsel for Mr. & Mrs. Gosselin,
7 Mr. & Mrs. Gionas, Mr. & Mrs.
8 Inwood, Mr. & Mrs. Turner,
9 Mr. & Mrs. Lutes, and Mr. &
10 Mrs. Murphy (parents of
11 deceased children)
12 F.J. SHANAHAN Counsel for Mr. & Mrs. Dominic
13 Lombardo (parents of deceased
14 child Stephanie Lombardo; and
15 Heather Dawson (mother of
16 deceased child Amber Dawson)
17 W.W. TOBIAS Counsel for Mr. & Mrs. Hines
18 (parents of deceased child
19 Jordan Hines)
20 J. SHINEHOFT Counsel for Lorie Pacsai and
21 Kevin Garnet (parents of
22 deceased child Kevin Pacsai)
23
24
25

VOLUME 87



E R R A T A

VOLUME 85 - 21 December 1983

Page/line

8567 3 "instant" should be: 'incident'

VOLUME 86 - 22 December 1983

Page/line

8724 20 "RN's" should be: 'RNA's'



INDEX of WITNESSES

| | |
|--|------|
| <u>MIRKIN</u> , Dr. Bernard L., Recalled | 8795 |
| Direct Examination by Mr. Lamek | 8795 |

INDEX of EXHIBITS

| <u>Exhibit No.</u> | <u>Description</u> | <u>Page</u> |
|--------------------|---|-------------|
| 313 | Memorandum Report by Dr. B. L. Mirkin, dated 29 December 1983, with 36 data sheets. | 8800 |
| 314 | Report of Dr. Moller | 8853 |



1 --- on commencing at 10:00 a.m.

2 THE COMMISSIONER: Before we
3 start this morning, I have a couple of matters.

4 I understand that the Atlanta
5 Report authors are scheduled to give evidence
6 starting on Monday, January 23rd. According to
7 the long-stated plan the full report will be
8 released to all counsel tomorrow, January 11th.
9 If there is some reason for further delay, obviously
it must be spoken to before the release.

10 I would like to emphasize that
11 document is, at this point, being released to
12 counsel only and is not available to the public.
13 If anyone should release it to the public, I can
14 offer you no protection from civil or criminal
15 action. When it becomes an exhibit, then of
course, it is a public document.

16 I am also prepared to give the
17 ruling on the Carol Brown statement. Before I
18 do that, I have received - and there was no require-
19 ment that anyone argue the matter, but I have
20 received an argument from Mr. Sopinka; another one
from Miss Kitely and another one from Mr. Labow.

21 Has anyone else submitted one
22 that I have not heard about?

23 Then, I will give judgment in
24 the matter.

25

10jan84
A
DMrc



1
2 This Commission is charged to
3 enquire into the cause of death of some 36 children
4 who died at The Hospital for Sick Children between
5 June 30, 1980 and March 22, 1981, and into the
6 investigation and prosecution of a nurse, Susan
7 Nelles, who was charged with the murder of four
8 of those children and discharged at the conclusion
9 of the preliminary inquiry.

10 The witness Carol Browne is a
11 nurse at that Hospital and has testified to the
12 procedures and events ~~during~~ the relevant
13 period. She is represented by counsel but there
14 is no shadow of suggestion that she was implicated
15 in the deaths.

16 In the course of the investiga-
17 tion, she was interviewed by members of the
18 Metropolitan Toronto Police and a document entitled,
19 "Anticipated Evidence of (the witness) Prepared." The
20 document is in the possession of the Commission and
21 I have examined it. It is largely in the form of
22 questions and answers but it is neither signed nor
23 acknowledged by the deponent. It was obviously
24 prepared by the police for their assistance in the
25 investigation.

Counsel for The Hospital for



1
2 Sick Children, one of the parties with standing at
3 the Commission, supported by other parties with
4 standing has asked for production of the document.
5 Counsel for the police is willing, but only with
6 the consent of the witness' counsel, and that
7 consent is not forthcoming.

8 The practice of the Commission
9 has been to provide to all witnesses, or potential
10 witnesses, prior to their giving evidence copies
11 of all statements made by them or attributed to
12 them, in our possession. We have also undertaken
13 to provide to any parties statements, or parts of
14 statements, made by or attributed to other people
15 which tend to implicate or exculpate that party
16 if we intend to adduce that evidence at the hear-
17 ing. I know of no rule of evidence that requires
18 that the statement be released to anyone but the
19 witness. On the other hand, there is equally no
20 rule for preventing its release where fairness
21 requires it. None of these documents, or this
22 document in any event, is claimed to be privileged.
23 It is important not to make a general rule in
24 the Commission, because many of the statements in
25 our possession contain much material which is not
only inadmissible and irrelevant but very prejudicial



1
2 in a non-legal sense to certain parties as well.

3 I think it is advisable to
4 make rulings for each statement only when asked and
5 only when the evidence of the author is tendered.
6 I have already ruled that when a witness has given
7 testimony adverse to a party that party's counsel
8 may see the statement to assist him in cross-
9 examination. I think also that when several
10 counsel have the statement and refer to it in the
11 course of ~~the~~ examination, it would be unreasonable
12 and perhaps unfair to withhold it from all counsel.
13 That position, in my view, was reached in the
14 evidence of Carol Browne. I will, therefore,
15 release her statement to all counsel and have her
16 recalled if any counsel wishes to cross-examine on
17 the statement. I would like, however, to emphasize
18 that the statement is not evidence of the truth
19 of the facts it recites, even though it might, in
20 some circumstances, become an exhibit. Its use is
21 solely for cross-examination. It was apparent from
22 some of the submissions that I have received that
23 the distinction was not clearly understood.

24 Yes, all right now, Mr. Lamek.

25 MR. LAMEK: Thank you, sir.

Mr. Commissioner, may I recall,



1
2 please, Dr. Bernard Mirkin.

3 DR. BERNARD L. MIRKIN, Recalled
4 DIRECT EXAMINATION BY MR. LAMEK:

5 Q. Dr. Mirkin, we are in less
6 lavish surroundings than we were when you first
7 appeared and you seem to be perched on a rather
8 high stool. If you are uncomfortable, let me know
9 and we can probably find a chair to substitute for
it.

10 You gave evidence in this
11 Commission, doctor, several months ago, and there
12 is, therefore, no need to go again through your
13 background and qualifications.

14 Perhaps I should remind everyone
15 that you were retained as a consultant to this
Commission, were you not?

16 A. That is correct.

17 Q. And you were asked to review
18 the Hospital records of and certain other information
19 about the 36 children whose deaths are under
20 review here.

21 Doctor, so that we may be sure
22 of what it is that you looked at, can you confirm
23 for me, please, that I supplied to you, for the
24 purpose of that review, copies of the 36 Hospital
25



1

2

records?

3

A. Yes, you did.

4

Q. And of the so-called Zebra
packages for the 36 children?

5

A. Yes.

6

7

Q. The toxicology reports of
Mr. Cimbura of the Centre of Forensic Sciences?

8

A. Yes.

9

10

11

12

Q. And I think I gave you
perhaps a copy of the scoring scheme devised by
Dr. Ralph Kauffman for his review of the charts
for the Metropolitan Toronto Police?

13

14

15

16

17

18

19

20

21

22

23

24

25

A. I think you did, but I
didn't review those at that particular point.

Q. But I did not give you his
scores that he attributed to the particular cases?

A. Correct.

Q. Now, prior to the time
that you completed your work and delivered your
report, did you receive any other material or
information about any of the children?

A. None.

Q. And just so we may be
absolutely clear, Dr. Mirkin, may I have it that a
copy of Dr. Kauffman's report was neither shown to



1

2

you nor its contents revealed to you?

3

A. That is correct.

4

5

Q. And, similarly, you did not see or become aware of the contents of Dr. Hastreiter's report?

6

7

A. Correct.

8

9

10

11

Q. And neither were you given any information about matters stated in evidence in this Commission or elsewhere by Dr. Kauffman, Dr. Hastreiter, Dr. Spielberg, Dr. McLeod or, indeed, any other person?

12

A. Correct.

13

14

15

Q. In short, Dr. Mirkin, your review, if I can put it this way, was a blind one and you were unaware of the conclusions reached by any other person with respect to these children?

16

A. That is correct.

17

18

19

20

Q. Since completing your work and submitting your report, however, you have received certain material and information from me as to the views expressed by others, have you not?

21

A. Yes.

22

23

24

25

Q. And in particular you have received a copy of Dr. Ralph Kauffman's report to the Metropolitan Toronto Police?



1

2

A. Yes.

3

4

Q. And you have now read that
report I take it?

5

A. I have.

6

Q. You have received from me a
copy of Dr. Hastreiter's report of his chart review?

7

A. Yes, I have.

8

9

Q. And you have considered that
report?

10

A. Yes.

11

12

Q. And you received from me a
copy of the transcript of evidence given here by
Dr. Steven Spielberg?

13

A. Yes.

14

15

Q. And you have read that, or
almost all of it, as I understand it?

16

A. Yes.

17

18

19

20

Q. And your report being dated
December 29th, I take it fairly, doctor, there has
not been a good deal of time between then and now
for you to read much more than the things I have
already outlined to you?

21

22

A. No, it's true - adequate
weekend material.

23

24

25

Q. Dr. Mirkin, can we look first



1

2

at your approach to the task that you undertook
for this Commission.

3

4

Can you tell us first what it was
that you were asked to do.

5

6

7

8

9

10

11

12

A. Our group was requested to
form some opinions regarding 36 patients at the
Children's Hospital in Toronto, in an effort to
ascertain the potential issue of whether digitalis
intoxication was present during the course of
hospitalization and also, at least in my judgment,
to determine whether the cause of death was anti-
cipated or unanticipated at the time it occurred.

13

14

15

Q. Were you also concerned,
doctor, to form an opinion if you could, on the
information provided as to whether digoxin played a
part in the deaths of any of the children?

16

17

18

19

20

21

22

23

24

25

A. Correct.

Q. Now, doctor, your report or
memorandum, copies of which have been circulated to
everybody, is dated December 29, 1983, and I have
taken the liberty of having it bound together with
some 36 data sheets, so-called, and we will come to
a description of those, which I have arranged
alphabetically, not in the code number sequence,
and according to the numbers which were attributed



1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25

to them.

Can you confirm for me, doctor,
that the document that I am showing to you is
indeed, with an added index, the memorandum report
that you submitted, together with the 36 data sheets?

A. Yes, that is correct.

MR. LAMEK: May that be the next
exhibit, please, Mr. Commissioner?

THE COMMISSIONER: Yes. Exhibit
313.

--- EXHIBIT NO. 313: Memorandum Report by Dr. B. L.
Mirkin, dated 29 December 1983,
with 36 data sheets.

MR. LAMEK: Q. Can we turn to
the first page of your memorandum report, Dr. Mirkin,
page 1 of the binder. It is addressed to this
Commission and it is from five physicians; that is
to say, from yourself, Drs. Green, Moller, O'Dea and
Sinaiko.



B: 1 And I take it from that and a comment
BM: 2 that you made a moment ago that the task was under-
yk 3 taken as a team project as it were?

4 A. That is correct.

5 Q. And the five whose names
6 appear on page 1 of the report, I take it the five
7 members of the team?

8 A. Yes.

9 Q. Was there any other member of
10 the team?

11 A. None.

12 Q. Perhaps you could just tell us
13 something very briefly about the areas of specializa-
14 tion and the qualifications of the other four?

15 A. Dr. Thomas Green is an
16 associate professor in the Division of Clinical
17 Pharmacology at the University of Minnesota. He
18 is trained as a pediatrician and a clinical pharma-
19 cologist and he has a Fellowship completed in the
20 latter discipline and is currently the Associate
21 Chief of the Pediatric Adolescent Intensive Care
22 Unit.

23 Dr. James Moller is a professor
24 in the Department of Pediatrics and is Associate
25 Deputy Chief of the Division of Pediatric Cardiology.
He is internationally known in this regard.

Q. At the University of Minnesota?

A. Yes.



B2

1 A. Yes. I'm sorry, all of these
2 are associated with the University of Minnesota.

3 Dr. Robert O'Dea is a PhD, MD,
4 pediatrician and pharmacologist whose specialty
5 has been the area of metabolic disease of the
6 new born. He is a member of the Division of Clinical
7 Pharmacology.

8 Dr. Alan Sinaiko is a pediatrician
9 who also completed Fellowship in Clinical Pharmacology
10 and his area of specialization has been kidney
11 diseases.

12 Q. As I understand it then we
13 have, including yourself, four clinical pharmacologists
14 and pediatricians, together with Dr. Moller, a
15 pediatric cardiologist.

16 A. That is correct.

17 Q. Now, you are identified in
18 the report, Dr. Mirkin , as the testifying
19 consultant and, indeed, here you are.

20 May I take it that if with respect
21 to any of the cases that we will discuss there was
22 any significant difference of opinion among the
23 members of the team, or indeed if there was even
24 one member who didn't agree with the others, you
25 will tell me as such cases arise?



B3

1

2

A. That is correct.

3

4

5

6

Q. And I won't need therefore to ask you with respect to each case whether the opinions expressed were unanimous, you will tell me if there was any difference of opinion?

7

8

9

A. Mr. Lamek, is it worthwhile, or should we do this later, in terms of the scores, just what that represents in terms of heterogeneity of opinion.

10

11

Q. Well, perhaps we could come to it in the course of looking at the methodology.

12

A. Fine.

13

14

Q. For the moment may I have it that any disagreement you will bring to our attention as we deal with the particular case?

15

A. Yes.

16

17

18

19

20

21

Q. Thank you. You have described in the first part of your memorandum report, Dr. Mirkin, the review process. Briefly, as I understand it, each of the four pharmacologists on the team, that is everyone except Dr. Moller, received a number of charts, they were distributed by you on a random basis?

22

A. Yes.

23

24

25

Q. And if we turn to page 3 of



B4

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25

your report where the patients are listed in the numerical sequence of the code which you ascribe to each chart, as I understand it numbers 1 to 10 were reviewed initially by Dr. O'Dea. Do I have that correctly?

A. That is correct.

Q. Numbers 11 to 19 were reviewed by Dr. Sinaiko?

A. Correct.

Q. Numbers 20 to 28 by Dr. Green?

A. Correct.

Q. And numbers 29 to 36 by yourself?

A. Correct.

Q. And as you have said in the report, Dr. Moller, the pediatric cardiologist, reviewed the zebra packages?

A. Correct.

Q. Did Dr. Moller also review the hospital charts themselves?

A. Not as a primary reviewer. This occurred during our integrated committee meetings.

Q. All right. Now, in paragraph 2 on page 1 of your report you say that a specific data form was developed. I take it, doctor, that was



B5

1

2

3

4

5

6

7

8

9

10

11

12

13

14

15

16

17

18

19

20

21

22

23

24

25

done to ensure uniformity amongst the several reviewers as to the information they were selecting for consideration?

A. Yes.

Q. And was that data form or data chart structured by agreement between the reviewing parties?

A. Yes. Everyone reviewed it and made suggestions.

Q. Perhaps we should just be clear that we understand what it is that is set out on the data sheet. Could we turn please to page 5 of the binder. That is the data sheet relating to the patient Adamo. I am not particularly interested in the information that is set out in it so much as in the structure of the form. In the first part, clearly, we've got some basic information about the patient himself, date of admission, date of birth and death and so on. And then in part 2 we have Diagnoses, both pre and post mortem. Did the post mortem diagnoses, Doctor, come from autopsy reports where such reports were available in the chart?

A. Yes, that's the source.

Q. And in the absence of an autopsy report, I take it we should expect to find



1
B6 2 the post mortem diagnosis part of this part 2 blank?

3 A. Correct.

4 Q. All right. In item No.3 there
5 is a subdivision of the clinical course information
6 and the first significant events occurring more than
7 a week prior to death and then significant events
8 occurring in the final week of life. Was the
9 determination of what was significant left to the
10 judgment of the individual reviewer?

11 A. Yes, this was essentially
12 left to the individual's discretion but in a
13 preliminary approach to this problem we decided that
14 certain pieces of information obviously would be
15 very important. So, significant events I presume -
16 well, significant events means, not presumption,
17 information that pertains to meaningful changes in
18 the status of the patient and also characteristics
19 of the patient's course that provide information
20 either about the stability of the patient or movements
21 away from stability of the patient.

22 Q. Dr. Mirkin, was each chart
23 read in its entirety by more than one reviewer?

24 A. The initial review was
25 carried out by one reviewer.

Q. And at any subsequent stage



B7 2 did any other reviewer reread the entire chart?

3 A. Yes, during our team meetings,
4 of which there were three, each patient was presented
5 by the primary reviewer in a case presentation format.
6 Then pieces of information were fed to the team at
7 that time. For example, with Patient No.12, that
8 is Adamo the one you are looking at.

9 Q. Yes.

10 A. We presented this at the
11 team meeting and then Dr. Moller the cardiologist
12 would present the electrocardiographic interpretations
13 from the zebra charts. We would have a group
14 discussion, members of the team would then ask for
15 pertinent pieces of information and if it was not
16 available would review the chart themselves. So,
17 at various times one to as many as three people might
18 have looked through that chart.

19 Q. Other than as may have
20 occurred as you have told us in the course of the
21 group meetings, the team meetings or discussions,
22 was there any other check or system of review of
23 the assessment of the intitial reviewer as to what
24 was significant in the chart? Is there any other
25 safeguard to make sure that he had not omitted
significant information?



B8

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25

A. No, we had no other review process.

Q. All right. Now, Item No.4 on the next page the form calls for information as to prescribed digoxin treatment and certain other information such as electrolytes, BUN, serum creatinine and serum digoxin concentrations, I take it, where they appear in the chart?

A. Correct.

Q. And on the next page in Section 5 the chart asks for a note to be made of evidence of digitalis intoxication. Can you tell me please whether that called for evidence of intoxication at any particular time or whether it included all times disclosed in the chart?

A. The entire course of the patient disclosed in the chart.

Q. So, if at any stage of the patient's course as it appeared from the chart there was something which the reviewer considered to be evidence of intoxication it would be recorded in Part 5?

A. That is correct.

Q. Why did you want to know that?



B9

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25

A. We felt that information describing the patient's sensitivity to or lack of sensitivity to digoxin therapy during the course of the management would be important in terms of defining perhaps the risk that this patient was at when exposed to this drug.



C:
DP:
yk

1

2

3

4

5

6

7

8

9

10

11

12

13

14

15

16

17

18

19

20

21

22

23

24

25

We also wanted to stress that the mere presence of the digitalis intoxication at some time during the hospitalization was not necessarily contributory to the demise of the patient.

Q. So Part V does not focus on death and cause of death. It focuses on the entire course of the patient and any evidence that may have occurred at any time during that course of digoxin intoxication?

A. That is correct.

Q. Part VI of the data sheet is headed "Drug Interactions" and I take it the reviewer was asked to note other drugs that were being administered to the patient which may have, as set out in there, influenced digoxin concentration or influenced the sensitivity of the patient to digoxin?

A. That is correct.

Q. We have heard something already, doctor, in the context of cross-reactivity about drugs which may influence recorded digoxin concentrations in samples. We have not heard very much so far about drugs which may alter the sensitivity of the child to digoxin. The printed form refers to diuretics, adrenergic agonists and antagonists, Perhaps you could tell us first what



C2

1

2

an adrenergic agonist and antagonist is, please.

3

4

5

6

7

8

9

10

11

12

13

14

15

16

17

18

19

20

21

22

23

24

25

A. The adrenergic nervous system is similar to the sympathetic nervous system. You can use those synonymously. It is what we all learned about in high school, "the flight or fight response" when your hair gets on edge and you start trembling and you have some rage. Generally that is the sympathetic nervous or adrenergic nervous system that is activated. I am sure everyone in this courtroom is familiar with that feeling.

Q. Sort of when the adrenelin starts pumping, is that what you mean?

A. That is right. An agonist is something that provokes a positive response in this context. A drug like adrenelin which was used as you know in the resuscitation of many of these patients would be expected to cause increased force of contraction of the heart, increased heart rate, and that would be an agonist stimulatory effect. The antagonist to this drug in particular would be a drug like propranolol which was used in some of these patients as well.

Q. Is the suggestion, Dr. Mirkin, that the administration of such drugs, diuretics and adrenergic agonist and antagonists



C3

1

2

3

4

5

6

7

8

9

10

11

12

13

14

15

16

17

18

19

20

21

22

23

24

25

is it that the administration of such drugs might cause a child to have a toxic reaction even perhaps to therapeutic doses of digoxin?

A. That is correct.

Q. Do these sensitizing drugs also have the effect of elevating serum digoxin concentrations?

A. In general the drugs that are listed here, the diuretics, the adrenergic agonists and antagonists and anaesthetics can be considered as generically not to increase the serum concentration, that is, not to increase.

Q. So the fact that, as you say, a diuretic or an adrenergic agonist is being administered, the fact that that may sensitize the child to digoxin is not going to explain an elevated serum digoxin concentration?

A. That is correct. The enhancement of the effect of digoxin produced by these agents is due to an effect these agents produce on the heart itself. I guess I have pre-empted your question, perhaps.

Q. No, no, you answered it for me, thank you.

Finally on page 3 of the data sheet,



1
2 we have Part VII "Indications for Digitalis Therapy".

3 THE COMMISSIONER: That is page 8,
4 is not?

5 MR. LAMEK: Page 8 of the binder,
6 page 3 of the data sheet, I think, sir.

7 Q. I'm not quite sure what it
8 is that you are looking for there and why you wanted
9 the information.

10 A. Presumably when anyone
11 administers a drug or when you treat someone there
12 should be a reason for giving it.

13 Q. Yes.

14 A. When we talk about indications,
15 that is generally the term that is used, and we listed
16 here two reasons why this would be given. One, for
17 treatment of the arrhythmia, generally speaking.
18 If you have a patient with a very rapid heart rate,
19 you have heard that digitalis can be used to treat
20 that patient. Secondly, patients with congestive heart
21 failure, as you know, it is used there. We were
22 concerned to make an attempt to define the appropriate-
23 ness of therapy. Since one of the issues here is
24 appropriateness or inappropriateness of therapy,
25 if we could define data to suggest that digitalis
treatment was used appropriately, then I think we



C5

1
2 all felt this was information that would bear on the
3 case evaluation. The EKG and echocardiogram here
4 really are pieces of information that we thought
5 also provided objective data about the clinical -
6 sort of re-affirmed or confirmed the clinical
7 diagnosis of congestive heart failure. Also it
8 provided us some information to see whether or not
9 the drugs were exerting an effect on rhythm, or
10 function of the heart.

11 Q. Finally in Part VIII on
12 what, with my apologies, Mr. Commissioner, is page 4
13 of the data sheet, page 8 of the binder, there is
14 the heading "Digitalis Intoxications" and there is
15 a space for "present" or "absent" which in the case
16 of this child is not completed, and I take it that
17 calls for the conclusion of the reviewer as to
18 whether the chart contains evidence of digoxin
19 intoxication?

20 A. That is correct, and I might
21 add that the evidence is based on not only objective
22 data such as electrocardiogram but information based
23 on clinical conclusions that were present in the
24 chart.

25 Q. I want to explore that for
just a moment if I may. Do I take it that what is
being recorded here is the presence or absence of



C6

1

2

3

4

5

6

7

8

9

10

11

12

13

14

15

16

17

18

19

20

21

22

23

24

25

what the reviewer considered to be digoxin intoxication at any time during the course of the child's hospital stay?

A. That is correct.

Q. We are not looking at this point for an assessment of digoxin intoxication in the death of the child.

A. That is correct.

Q. We are looking solely at the clinical course as disclosed by the chart.

A. Correct.

Q. As to the evidence, can you tell us with perhaps a little more particularity than you did a moment ago, Dr. Mirkin, what were considered to be significant pieces of evidence in coming to the conclusion that at some time or other this child had indeed suffered from digoxin intoxication?

A. Well, we used some of the standard reference points such as the presence of specific types of symptoms, some of which would be nausea, vomiting, diarrhea, the presence of rhythm disturbances and in this regard we used the electrocardiogram to confirm what might have been clinically described changes in rhythm. For example for patients



C7 1
2 with a pulse rate changed dramatically, the EKG
3 provided important objective confirmation of what
4 changes were going on in conduction, in the
5 abnormalities of the heart. We also used physical
6 findings presented in the chart. These relate more
7 to the patient's liver being up or down, you have
8 heard that term before; whether or not the patient
9 was showing any signs of a change in the degree of
10 discomfort. Very commonly one can discern digitalis
11 intoxication by the fact that the patients don't
12 improve in their course but become progressively worse.
13 That may be a bit confusing but the general use of
14 digitalis is to improve the function of the heart.
15 As one increases the amount to a point that may
16 produce toxicity rather than increasing the function
17 of the heart one tends to decrease its capacity to
18 function and the heart failure may become progressively
19 worse. That is a subtle sign of digitalis intoxication
20 and certainly it does occur, so we were using these
21 general guidelines.



1

10jan84

D

DMrc

2

Q. There is one piece of evidence

3

that you have not mentioned that I would have
thought might have been taken into account; and that
is a biochemistry report in the lab as to digoxin
levels that were taken in the monitoring program.

4

5

6

7

8

9

10

11

12

13

14

A. Yes. That information
of course is integrated into this process, but I
think it is important to emphasize that digitalis
levels per se are not the sine qua non of
digitalis intoxication. I think that point is
important. There can be a disassociation between
an elevated blood level and a toxic effect and I
am sure we will discuss that in greater detail
later.

15

16

17

18

19

Q. In forming the conclusion
as to whether the chart disclosed evidence of
digoxin intoxication at any time in the child's
course, Dr. Mirkin, was there any one kind of
evidence that was regarded as essential to the
forming of that conclusion?

20

21

22

A. Well, I think it should be
recognized that there was some patients in whom
we did not have very effective and meaningful
electrocardiographic data.

23

24

25

Q. Yes.



D2

1

2

3

4

5

6

7

8

9

10

11

12

13

14

15

16

17

18

19

20

21

22

23

24

25

A. I think I would like to emphasize that the decision by each reviewer was made based on a synthesis of all of the information available. It is hard to answer that question specifically.

To put it in another way, if I may reinterpret it?

Q. Yes, of course.

A. Would we have made the diagnosis of digitalis intoxication in the absence of certain pieces of information? I suppose under the circumstances we were charged to come up with an observation whether dig. intoxication was present or not, and we reached that conclusion in some cases where the data base was not as complete as in others. So we reached this conclusion based on all of the available data that permitted us to reach a meaningful conclusion.

When I say that, it may sound like doubletalk, but it can be revised.

Q. Perhaps I can put it this way, doctor: Could an opinion that digoxin intoxication had occurred be reached in the absence of electrocardiographic evidence of digoxin intoxication?

A. We would not have reached a



D3

1

2

conclusion based on that alone.

3

4

Q . Would you have reached it
in its absence?

5

A. Yes.

6

7

Q. So there was no one piece
of information that was essential to the overall
conclusions?

8

9

A. That is what I am trying to
say.

10

11

12

13

Q. Now in reviewing the
charts, Dr. Mirkin, and in completing the data forms,
did the reviewers give any weight to post mortem
digoxin levels, blood or tissue?

14

15

A. Well not in the initial --
not in the evaluation or determination of the score
that you see recorded.

16

17

18

19

20

Q. I would take it from the
text of your initial report that the reviewers were
not given, or made aware of, the Centre of Forensic
Sciences information prior to their completion of the
initial reviews?

21

22

A. That is correct. Only to
the extent that, in some charts, there were fragments
of those data perhaps placed in the reports.

23

24

25

Q. I would like to know what



D4

1

2

3

4

5

6

7

8

9

10

11

12

13

14

15

16

17

18

19

20

21

22

23

24

25

was made of those, and, as you say, in some few of the Hospital charts, digoxin levels in post mortem blood samples were recorded at the Hospital and indeed some immediate ante mortem samples were included.

Can we look, for example, at page 93 of the binder, the Miller chart, which I think is your Code No. 35.

This is a child whose chart you reviewed, Dr. Mirkin, Allana Miller.

At page 94, the second sheet of the chart, there is a notation which I would take to be yours, that the chart discloses a post mortem serum concentration of - you record it as greater than 78 nanograms per millilitre, and my recollection is it was 78.

That information came from the chart when you reviewed the chart I take it?

A. That is correct.

Q. Where such data appeared in the chart, were they taken into account in forming your opinion as to whether this child had, at some time in its hospital course, suffered from digoxin intoxication?

A. No. Those particular data



1

D5

2

3

4

5

6

7

8

9

10

11

12

13

14

15

16

17

18

19

20

21

22

23

24

25

were not used in the determination of digitalis intoxication.

Q. And indeed when I look back to your report at page 4 - and it is also page 4 of the binder, Code No. 35, Allana Miller, and I am anticipating for a moment the scoring system, but she is given a score of zero, which as I understand it, is indicative of the conclusion that on a review of the chart it was unlikely that she had suffered during her hospital stay from digoxin intoxication.

A. That is correct.

Q. I guess the point we have to emphasize, doctor, as I understand it, the review, as disclosed in your memorandum report and in the data sheets and the scoring set out in your memorandum report, it is not directed to digoxin intoxication as an involved element in the death of the child but rather to an episode during the life of the child?

A. That is correct.

Q. You have told us that after these charts were reviewed by the persons to whom they were distributed, there were meetings held to discuss them and that Dr. Moller provided information



1

D6

2

3

4

5

6

7

8

9

10

11

12

13

14

15

16

17

18

19

20

21

22

23

24

25

to those meetings from the Zebra charts and his reading of the electrocardiogram tracings, and you provided information as to the toxicological data produced by Mr. Cimbura at the Centre of Forensic Sciences.

Now, other than telling the group of his interpretations of the EKGs in the charts, did Dr. Moller provide any other input to the group?

A. Yes. We were very concerned to enquire about the potential for sudden death, or death occurring in this particular type of congenital lesion in the patient; so, one of the advantages of this approach was to have an extremely skilled and experienced pediatric cardiologist assisting us at the time of our review process, giving an impression based on his experience about the possibility that such a patient with such a lesion of the heart might experience a death as might have occurred in this particular patient. So that was very helpful, and we had his clinical interpretation of the disease state as well as our interpretation, analytical interpretation, of data made available to us in the chart.

Q. And there were three such



D7

1

2

3

4

5

6

7

8

9

10

11

12

13

14

15

16

17

18

19

20

21

22

23

24

25

discussion meetings. I take it not every chart was discussed at each of the three meetings?

A. You take it correctly.

Q. At Meeting 1, you discussed the first dozen or so, and so on?

A. Correct.

Q. As a result of all that, was a consensus or perhaps an agreement to differ in some cases arrived at with respect to each child as to the likelihood that, at some time, in his or her course, there had been one or more episodes of digoxin toxicity?

A. Yes. That is essentially the conclusion we reached.

Q. And those opinions are set out on pages 3 and 4 of your report, pages 3 and 4 of the binder, the scoring system being explained on page 2; a score of 0 to 3, meaning that it was unlikely there had been any digitalis intoxication; a score of greater than 3 and up to 7 meant it really was not very clear whether there may have been; and greater than 7 and up to 10, an indication that it was considered likely that there had been one or more episodes of digoxin intoxication?

A. Yes.



D8

1

2

3

4

5

6

7

8

9

10

11

12

13

14

15

16

17

18

19

20

21

22

23

24

25

Q. And the scores which are
said to be mean values are recorded on pages 3 and 4.

Can you tell us please, in what
sense they are mean values?

A. They are the composite
average of five individual scores provided by each
of the members of the team. They don't show the
heterogeneity of the scoring but, as Mr. Lamek
mentioned, first of all, I will apprise you of
any discrepancies that came up in our evaluation
between members of the team. The extraordinary
thing I think was the unanimity in a sense of the
group, who were not prone to agree on most things.
So I think there was a very positive aspect of
this review process.

Q. Doctor, at the risk of
unnecessary repetition - because I confess, when
I first read this report, I was a little unclear as
to what it meant - may I be absolutely clear now
that the scores assigned to the several children
are not meant to be any assessment of whether
digoxin toxicity played a part in the deaths of
those children?

A. Yes, I think that is a
correct conclusion.



D9

1

2

3

4

5

6

7

8

9

10

11

12

13

14

15

16

17

18

19

20

21

22

23

24

25

Q. They merely show the likelihood, in the collective judgment of your team, of digoxin toxicity having occurred at some time during the child's course, as disclosed in the charts and the Zebra packages?

A. That is correct.

On page 2 of this document, paragraph D --

Q. Yes.

A. -- the last sentence I think paraphrases what you have just said; isn't that correct?

Q. Yes, I think so.

Indeed, the score is entirely neutral on the question of whether digoxin was involved in the death, was it not?

A. As much as anything can be.

Q. You say:

"It should not be concluded that death of each subject was attributed to digoxin intoxication, per se."

If I were to read it as saying it should not be concluded that the death of each subject was or was not attributable to digoxin intoxication, per se, that I take it would



1
D10 2 accurately reflect the meaning?

3 A. Yes. I think that is
4 correct.

5 Q. So, looking at these scores,
6 the fact that David Taylor - the first child on
7 page 3 - was rated 9, does not per se mean that
8 there was any judgment that he very likely died of
9 digoxin toxicity?

10 A. That is correct.

11 Q. And equally, on page 4,
12 the fact that Justin Cook, No. 34 was scored zero,
13 does not reflect any judgment that he did not die
14 of digoxin toxicity?

15 A. Yes.

16 Q. Indeed, doctor, at any point
17 in this memorandum report or, indeed in the data
18 sheets which are found with it, do you express any
19 opinion as to whether digoxin played a part in the
20 death of any of these children?

21 A. No, we do not.

22 Q. But that question was, I
23 take it, considered?

24 A. Yes.

25 Q. And judgments and opinions
were formed as to particular children, I take it?



D11

1

2

3

4

5

6

7

8

9

10

11

12

13

14

15

16

17

18

19

20

21

22

23

24

25

Q. Those judgments, of course, are of primary interest to this Commission, and I will be coming back to them shortly.

First, let me complete the review of what is contained in your memorandum report.

On pages 3 and 4, there is a "Comment" column, and a number of children have asterisks against their names.

At the foot of page 4, or at the foot of the column on page 4, the asterisk is said to be indicating that the death of the patient was unanticipated at the time, based on the clinical history documented in the charts. In other words, the death was not expected to occur when it did, on the basis of the clinical condition and course?

A. Yes.

Q. Why is that recorded in this report, doctor?

A. Well, considering the concerns that were part of our initial charge in the review process, we felt that it would be helpful to identify individuals who appeared to be in reasonably stable condition right up prior to the time of death, and we identified individuals who



ANGUS. STONEHOUSE & CO. LTD.
TORONTO, ONTARIO

Mirkin
dr.ex. (Lamek)

8828

D12 1
2 displayed these characteristics, whether or not
3 the death was due to, or presumably associated with
4 the presence or absence of digitalis.

5

6

7

8

9

10

11

12

13

14

15

16

17

18

19

20

21

22

23

24

25



E:
BM:
yk

1

2

3

4

5

6

7

8

9

10

11

12

13

14

15

16

17

18

19

20

21

22

23

24

25

So, these unexpected deaths have nothing to do necessarily with the presence or absence of digitalis administration or the presence or absence of digitalis in post mortem specimens. We felt these were just unanticipated deaths and we could explain those as we go along.

Q. Well, we will want to look at some of them, doctor, but do I understand you that if a death or the time of a death was not thought to be sufficiently explained by the clinical course as disclosed in the chart, that was noted with an asterisk as a death which raised a question which had to be resolved?

A. That is correct.

Q. All right. If an answer were possible?

A. Yes.

Q. Yes. Now, what was the basis for making the comment that a death was unexpected. We know from the evidence that we have heard and the charts that we have read here, Dr. Mirkin, that in some cases a death is described in the chart as being unexpected or sudden and unexpected. Was that an element in making the comment in any particular case?



1
2 A. In general what we attempted
3 to do with the imprecision of this approach, which I think
4 must be recognized, we took wherever possible the
5 available clinical data and the notes contained in
6 both nursing and physician reports to reach some
7 understanding of the patient's condition during
8 this last week of life, let us say. If in our
9 opinion the data suggested a stable course with an
10 unexplained deterioration in the status of the patient,
11 we put those patients in these columns called
12 comments where an asterisk designates such a course
13 of events.

14 Q. Now, doctor, there are nine
15 children of the 36 whose deaths are so characterized,
16 unanticipated at the time. May I ask you about
17 certain other children in this list whose names
18 aren't asterisked. Perhaps you could tell me please
19 what it is about those children's conditions that
20 led you to believe that the death was not unexpected.
21 Forgive me for all the negatives in that but I think
22 you follow my meaning, do you? For example, chart
23 code No.5, Velasquez. Was that in the view of your
24 reviewers a death which was not unexpected when it
25 occurred?

26 A. Yes, we didn't designate that



1

2

but I want to look at my chart.

3

4

Q. Would it be of any assistance
to you to have the chart available to you?

5

6

A. No, I have it here, I will
dig it out.

7

8

Q. I mean the actual medical
chart.

9

10

11

12

13

14

15

16

17

18

19

20

21

22

23

24

25

Q. No, I think the summary charts
usually have sufficient information. There were cases
you see where we concluded that the death of a child
was not unexpected because there had been some general
deterioration in the state of the child and this was
not a precipitous event. For example, with this
particular patient, this patient was operated on in
August, August 21, 1980 and really had an uneventful
post-operative course, as I think Dr. Lamek - Mr.
Lamek is attempting to indicate. On August 23rd,
1980, the baby developed fever and a rapid heart rate.
We interpreted the fever and the sepsis that developed
in this patient as being indicative of a rather
drastic change in the condition and the patient went
downhill from there. We saw that as being consistent
with an unanticipated death in this patient. Now,
the question might be raised why this baby developed
fever and a rapid heart rate perhaps but I don't think



1
2 we had any information to determine the cause of
3 that other than to assume it was a post-operative
4 infection that the baby did not recover from.

5 So, in that particular patient we
6 had no evidence here of digitalis intoxication to
7 the best of our knowledge and we concluded this was
8 not an unanticipated death.

9 Q. Perhaps I could ask you to
10 take a look at the chart, Dr. Mirkin, and maybe the
11 Registrar could put it in front of you. It is
12 Exhibit 54, Mr. Commissioner.

13 THE COMMISSIONER: I'm not sure what
14 you are saying, Doctor. Are you saying this was an
15 anticipated death?

16 THE WITNESS: No, I am saying - oh,
17 well, as much as death can be anticipated. I think
18 that the events here correlate most closely with
19 the administration of a dose of codeine and a dose
20 of a drug that was used as an antedote to the codeine,
21 naloxone. I would say that we had no data here
22 to think that this death was unanticipated at the
23 time. Is that clear, Mr. Grange?

24 THE COMMISSIONER: It's not really.

25 THE WITNESS: No, go ahead.

THE COMMISSIONER: It isn't clear to



1
2 me because at one point you were saying that he had
3 an uneventful post-operative course. Supposing he
4 did die of codeine and the reaction to a drug, would
5 you not have called that an unanticipated death or
6 would you have called that an anticipated death?

7 THE WITNESS: Oh, I think that is
8 an unanticipated death, supposing. But that type
9 of reaction is a very unusual one and I would say
10 that the burden of proof is on my shoulders to
11 conclude that.

12 THE COMMISSIONER: Well, I can under-
13 stand that but we will probably have to look at some
14 of the others but if you take for instance - well,
15 I'm sure you are going to deal with some of these
16 others too?

17 MR. LAMEK: Yes I am indeed, Mr.
18 Commissioner.

19 THE COMMISSIONER: I would have
20 thought Velasquez was probably the most unusual death
21 of all, of all of these, but the most unanticipated,
22 although, it may be explained by the naloxone.

23 THE WITNESS: Well, excuse me.

24 THE COMMISSIONER: But you don't agree
25 with that?

THE WITNESS: That's an unusual ---



1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25

THE COMMISSIONER: Some of the evidence we got was it was the most unexpected death.

THE WITNESS: It may be unexpected in the sense that here is a patient - it is unexpected in the sense that here is a patient with a congenital defect that is amenable to repair and had been repaired and then two days later the baby developed fever and a rapid heart rate. Now, we thought that the baby had become infected now, which is not an uncommon possibility because one had to eliminate the possibility of sepsis. The demise of the baby in that sense, I suppose, a child with this degree of impairment, you would have generally expected to come through, I think that is correct, I would agree with you on that.

The unexpected nature of it is there I suppose but it is difficult for me at least to say that a patient with fever and a rapid heart rate would always survive this course of events. I think that when we reviewed this we did not feel that there was any basis to think that this patient would have survived this event considering the degree of fever and the degree of heart failure that was present. What the cause of that was I couldn't comment on.



1

2

3

4

5

6

7

8

9

10

11

12

13

14

15

16

17

18

19

20

21

22

23

24

25

MR. LAMEK: Q. Could we examine that for a moment though, Doctor. The chart is now available to you I think. First with respect to the possibility of sepsis. Could we look at page 85 of the chart. The numbers are in the top right-hand corner. They are not always terribly clear I confess, it is 000085, which is the first of three bacteriology reports?

A. Yes.

Q. First recording that no organisms seen, the microscopy report, no growth after 48 hours of incubation, subsequently no growth, on the next page, after 21 days incubation, and the same thing on the next page. There does not appear to be any laboratory evidence of infection, does there?

A. No, there certainly isn't, but I would emphasize that very commonly it is not discernible particularly when a patient has been put on an antibiotic. So, that may be obscured. The fact that the patient had fever would suggest that there was some process going on. I wouldn't want to stand here categorically and defend that position.

Q. No, I understand that.



1

2

3

4

5

6

7

8

9

10

11

12

13

14

15

16

17

18

19

20

21

22

23

24

25

A. Only to emphasize that the patient with a very rapid heart rate with an increased elevated fever, temperature, that infection is a very high likelihood, so, please don't ...

Q. No, I understand.

A. ... omit that.

Q. Could you - I'm sorry, I didn't mean to interrupt you.

A. No, it's all right, go ahead.

Q. Could you turn to page 4 of the chart, Doctor, 000004. Now, that is a resume of events leading to the death of the Velasquez baby and it is written I tell you by the resident who administered the naloxone and who no doubt was a concerned young physician at the time.

It records that, and the references are in the chart, I can direct you to them if it be necessary, Doctor, from 1:30 on August 23rd the patient was noted to have fever and tachycardia. But halfway down the page in the central paragraph, in the paragraph beginning:

"On the recommended action of the cardiology fellow ..."

A. I am sorry, I have lost you. What page are you on?



1

2

Q. 000004.

3

A. Yes, mine reads, this is a

4

path report.

5

THE COMMISSIONER: This may be one

6

of those ---

7

MR. LAMEK: This may be one of those

8

with a double numbering system.

9

THE WITNESS: Oh, okay.

10

Q. It is at the very beginning
of the thing. It does start renumbering I'm afraid.

11

A. Okay, thank you.

12

Q. It is the actual fourth page
of the report.

13

A. Yes, thank you.

14

Q. That is the note written by

15

the resident who administered the naloxone following
the administration of which the child arrested.

16

17

A. Yes.

18

Q. And recorded that on August

19

23rd for 1:30 there was the fever, as you have said,

20

and the tachycardia. The middle of the page, the

21

second sentence of the paragraph that begins "On
the recommended action ---"

22

"When last observed at 1:00 a.m. on

23

August 24 Antonio was sleeping,

24

25



1

2

"breathing easily, was afebrile,

3

had a hear rate of 130 to 40 per

4

hour according to monitor."

5

A. Yes.

6

Q. And it does appear at least at

7

that time, does it not, Doctor, that the fever and

8

the tachycardia were under control shortly before his
death?

9

A. It certainly does.

10

Q. I have to ask you, in light

11

of that observation is it your view that the death

12

of Velasquez was not expected at the time that it
occurred?

13

A. Yes, I think had we picked

14

this up perhaps this would have modified our opinion

15

somewhat. As one examines this and using the criteria

16

I have outlined, this would have been a patient that,

17

based on the primary pathology existing here, based

18

on the apparent response to the surgical intervention,

19

successful response, based on the fact here that

20

the patient was stable at this time, as late as

21

this, I think I would have concluded that this was

22

an unanticipated death at this time.

23

Q. Certainly, Doctor, there are

24

the symptoms displayed on the 23rd for which there

25



1
2 is no apparent explanation, but I can only tell you
3 that the evidence here has been that the death of
4 this child at the hospital itself caused considerable
5 surprise.

6 A. Well, I think on that point,
7 you know, words are words of the wise, of course,
8 this is the sort of patient where the surgical
9 intervention is so often very successful. So, in
10 that sense I'm sure the institution people there
11 were surprised at the outcome. Now, reading this
12 piece of information I think it does tend to tip
13 our interpretation in a somewhat different - I
14 see this patient in a somewhat different light than
15 we did originally. For some reason we missed this
16 particular point.

17 Q. Okay. Doctor, could I then
18 ask you about the Dawson baby who is No.7, Amber
19 Dawson, Chart Code No.7. Can you tell me please
20 the basis upon which your team concluded that the
21 death of that child was not unexpected?
22
23
24
25



1

10jan84
F
DPrC

2

3

4

5

6

7

8

9

10

11

12

13

14

15

16

17

18

19

20

21

22

23

24

25

Again, if it would help you to have the Hospital record, it could be put beside you very quickly.

A. Well, this baby had a very significant pathology. This baby had undergone two procedures; one, to reduce the pressure in the pulmonary artery, put banding on it - and that was not terribly effective. Then, the band was taken off. I think this baby, overall- low birth weight, cyanotic, along with malnourished and failure to thrive - so, this is a very high risk child. I think this was perhaps part of the conclusions that were reached. The baby had had pneumonia on July 23 and seizures in the final two days of life. I think it was significant pneumonia in this particular patient, and bilaterally.

So, the conclusion that was reached in our review ~~these~~, I think you can all see this, was that there was no evidence of digitalis intoxication present but there is a note here that the cause of death was unclear.

What number is that in your list, Mr. Lamek?

Q. Code No. 7.

A. Yes. How would that come out



F2

1

2

in your book?

3

4

Q. It is found on page 21 of
the binder, but Exhibit 59 is the Hospital record.

5

Is that what you are looking for?

6

7

8

A. No. I think if you look at
page 24 of the document you have entered in, you will
see, on line 4, the statement, "Cause of death
unclear".

9

10

11

12

13

14

15

16

Q. Yes.

A. Whether that should be put
into the category of unanticipated is a moot point.
I do not think I would. I think that here is a
baby who is really quite ill and I don't recall,
in our discussion, that there was any feeling on the
part of the staff that the death of this baby was
unusual, or not in keeping with its hospital experience.

17

18

19

20

21

22

23

24

25

Q. Very well, doctor.
Frankly, I raised the question of
Amber Dawson, the expectedness or unexpectedness of
her death at the time that she died, because we have
heard opinions here that not only was there some
question as to the cause, but according to, as I
recall it, Dr. Rowe, he did not consider her at risk
of death at the time she died, and Dr. Nadas
has apparently delivered the view that her death at



F3

1

2

3

4

5

6

7

8

9

10

11

12

13

14

15

16

17

18

19

20

21

22

23

24

25

the time it occurred was inconsistent with her clinical condition. But different people can look at the same evidence in different ways.

A. I think so. We certainly could not come up with any further enlightenment on that particular point.

Q. The next child I ask you to examine for a moment, doctor, is David Taylor, who is Chart Code No. 1, page 121 of your binder.

Could you help me there, please, as to what it was in that child's course that led your team to the conclusion that this was not an unexpected death?

A. Well, I think that this particular patient's problem - aortic stenosis - and if we look at the post mortem report, this baby had a variety of other lesions. It was the opinion of our cardiologist that this was generally a fatal congenital cardiac disease, particularly with the constellation of associated abnormalities this infant had.

Now, I think it is important to recognize that the cause of death here, or the death that occurred, we felt was associated with digitalis intoxication.



F4

1

2

3

4

5

6

7

8

9

10

11

12

13

14

15

16

17

18

19

20

21

22

23

24

25

When you say unanticipated, in this particular patient, there was, I think, very clear evidence - or at least we could not exclude, let me put it that way, could not exclude that digitalis intoxication was present. This was based on rhythm disturbances that are described in this patient's clinical course all along. This patient had rhythm disturbances early on and, during the last few days of his hospitalization, these became prominent.

There are points in this particular chart, I think, that are consistent with dig. intoxication, even though we put down, "Could not determine in this child". I think that, again, the fact that we did not say that this patient was dig. intoxicated was -- I'm sorry, this is David Taylor. Excuse me. David Taylor was clearly dig. intoxicated - I was looking at the wrong one - because we gave him a rating of 9, and we felt that the demise of the patient was due to the arrhythmias that developed as a consequence of this.

Q. In that regard, doctor, do I take it that the case of David Taylor was one on which there was a difference of opinion on the team?

You are quite right, you gave



F5

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25

David Taylor a score of 9, but when I look at the review sheet, the chart having been reviewed by Dr. O'Dea, he says he cannot determine whether digitalis intoxication was present:

"Very difficult to assess. Patient has life-threatening, probably fatal, congenital cardiac disease, which appeared to respond to digitalis. However, patient on diuretics and death preceded by emesis. EKG changes which could be secondary to digitalis. However, severe aortic stenosis and endocardial fibrillation - myocardial or conduction pathway ischemia."

A. Yes.

Q. Conclusion:

"Digitalis intoxication cannot be excluded."

A. Yes. But the point that has to be made is that these initial reviews were made by single individuals.

Q. Yes.

A. What happened very often was that, in the course of the discussions, when the



1
2 evidence was aired out in a more detailed manner,
3 opinions we moved - and I think in this particular
4 one, Bob O'Dea concurred with us - along the line, and I
5 want to make that clear; the presence or absence
6 statement on this particular document may sometimes
7 be at variance with the overall score.

8 Q. That is the jumping-off
9 point for the discussion, I take it?

10 A. Exactly.

11 This particular patient is sort
12 of complicated because of the fact that we were
13 attempting to base the diagnosis of digitalis
14 intoxication on changes, abnormalities in the
15 rhythms of this patient. However, this patient had
16 a disease that involved that part of the heart where
17 the impulses are formed and where they are conducted;
18 so you have an intrinsic abnormality in the heart
19 that can produce changes in the electrocardiogram
20 that are not dissimilar to those that might be seen
21 with digitalis intoxication. That is, I think, the
22 ambiguity of the language.

23 Does that come across clearly,
24 what I am saying?

25 Q. I understand that. I take
it it was less ambiguous to you when you met in



1
2 discussion, particularly with Dr. Moller, than it
3 had been apparently to Dr. O'Dea on his initial
4 review?

5 A. That is really how we came
6 up with such a high score. You see, one low score
7 would tend to pull this ranking all the way down;
8 so, there was quite a bit of unanimity, I think, in
all of this.

9 Q. With respect to the question
10 with which we started, Dr. Mirkin; that is to say,
11 whether Taylor's death was expected or unexpected,
12 putting the cards face up on the table, I can tell
13 you that that is a matter upon which there has been
14 already a division of opinion in the evidence we have
heard in this Commission.

15 I was interested to know the basis
16 upon which your team fell on one or the other side
17 of the line.

18 A. Yes. I think that one of
19 the things that might be somewhat surprising here
20 is the fact that this patient did have evidence,
21 certainly, of digitalis intoxication, in your
22 opinion. In fact, it was quite clear. One might
23 have thought that perhaps a patient like this could
24 have survived but, again, I would have to venture
25



1

2

the opinion that this was due primarily to the
digitalis.

3

4

5

6

7

Q. Looking next to Kevin
Pacsai, No. 30 in your coding, page 109 of the
binder, that is a child whose death is not indicated
as having been considered to have been unexpected.

8

9

10

I would be grateful if you could
tell us, doctor, the elements in that child's
course which led your team to conclude that that
was not an unexpected death.

11

12

A. I will be with you in a
moment.

13

14

15

Q. Yes, of course. Anytime
you think it will be of assistance to you to look
at the complete chart, Dr. Mirkin, please say so,
and we will provide it right away.

16

17

A. I am looking for Dr. Moller's
report. Here we are.

18

19

20

21

This patient, Kevin Pacsai, had
paroxysmal atrial tachycardia, which was the pre
mortem diagnosis, which is a very rapid heart rate,
which is, essentially, what this baby had.

22

23

24

25

This baby also had, one week
prior to the death of the baby, five days prior, a
very, very severe illness, characterized by septic



1
2 shock. So this baby, prior to coming into The
3 Sick Children's Hospital, had been very, very ill.

4 However, in the notes, as of
5 3-8 and 3-11, when the baby was in Sick Children's
6 Hospital, the notes suggest that this baby was
7 considered to be stable, and we had, I think,
8 incontrovertable evidence that this baby was
9 digitalis intoxicated and concluded that the death
of the baby was associated with this phenomenon.

10 So, in a sense, you say, well,
11 is that not unanticipated. I suppose one could use
12 the term "unanticipated" but it is anticipated in
13 the light of the data that was available.

14 You have a baby with an extremely
15 severe heart block. You have a baby here with heart
16 rate decreased to 50. You have evidence that there
17 were large amounts of digitalis in this baby, toxic
18 levels, and when a patient presents that way, is that
19 indeed an unanticipated death? No. That is a
20 poisoning, in a sense, if you want to use that term -
therapeutic, perhaps, I will use - therapeutically-
21 induced overdose, if you want to use that term.

22 I would not consider the death
23 of the baby unanticipated. It could be a logical
24 consequence of what we observed. That is the point,
25



ANGUS. STONEHOUSE & CO. LTD.
TORONTO. ONTARIO

Mirkin
dr.ex. (Lamek)

8849

1

2

I think, that is causing some confusion here - if I
may attempt to explain it.

4

5

6

7

8

9

10

11

12

13

14

15

16

17

18

19

20

21

22

23

24

25



1

G:
DM:
yk

2

3

4

5

6

7

8

9

10

11

12

13

14

15

16

17

18

19

20

21

22

23

24

25

Q. Yes I think it is causing some confusion Dr. Mirkin if I may say so. Do you draw any distinction between a death which is not only attributable as to its occurrence but as to the time of its occurrence, to the, what I can call the physical clinical disease condition of the child and one which may be attributable to the treatment of that condition.

A. Oh!

Q. You seem to be suggesting, one, with respect to Pacsai is that although death may have been unexpected in terms of his actual physical condition maybe the treatment caused it.

A. Yes, I think that is probably a correct interpretation and I probably am making that distinction. It is probably ill-advised when I review the term "unanticipated". Well, you never really anticipate death I suppose in the treatment of the patient. I think though that there was sufficient data here to suggest that the treatment here was very contributory to the death of this patient. So in that sense it is not anticipated - I am sorry, it is not unanticipated, okay. In the other context a patient with this diseased state would not have been expected to die, so it was not unanticipated



1
2 in another sense. So I think if somehow I can get
3 that designation clearer we might want to put this
4 patient into the unanticipated category, I would
5 have no problem with that.

6 I guess what we tried to do was
7 identify individuals where there might have been a
8 reasonable cause for the death, and say, well, those
9 are not unanticipated and the reasonable cause here
10 was the fact that there was a lot of digitalis here
11 and this patient was showing overt and extremely
12 severe symptoms from that which could not be reversed
successfully.

13 Q. I wanted to come back to this,
14 but I think you said something which may be of
15 great significance, Doctor. You were referring to
16 an intoxication caused by the treatment of the
17 child. I would take it that the inference from that
18 is, as you suggested earlier, an intoxication induced
by a therapeutic administration of the drug.

19 A. Strictly an inference on my
20 part.

21 Q. Yes.

22 A. I feel that is the important
objective of the decision I want to maintain.

23 Q. Can we really say any more
24
25



1

2

than intoxication caused by digoxin?

3

4

A. In reality one could not, but you don't want to take the pejorative position on this thing, I don't.

5

6

7

8

9

Q. No, I'm not suggesting you should, but I do suggest Doctor, that while I would invite you to tell me the basis upon which you think one must assume intoxication resulting from therapeutic administration.

10

11

12

13

A. Strictly on historical premise, that what we read in the chart was the amount given and that is solely the basis for that judgment.

14

15

16

17

18

19

20

Q. Doctor you referred a moment ago to the report of Dr. Moller. You provided to me this morning, and I'm afraid I have had no opportunity to do more than merely copy a number of sheets I understand prepared by Dr. Moller, prepared on his instructions, dealing with each patient and his observations from his review because these were facts and such other material as he looked at?

21

22

23

24

25

A. That is correct.

Q. Have I correctly described the package you gave me this morning?

A. You have.



1

2

3

4

5

MR. LAMEK: Mr. Commissioner, I have distributed that just now to counsel since there has been reference to those documents perhaps they should be marked as the next exhibit.

6

7

8

THE COMMISSIONER: Yes, all right, Exhibit 314. Since nobody has read it would this be a good time to rise? Yes, all right.

9

--- EXHIBIT NO. 314: Report of Dr. Moller.

10

11

12

13

14

MR. LAMEK: I mark it now really because there has been no reference to it.

15

16

17

Q. Without being critical of Dr. Moller or anybody else, they apparently were not trying to proof read the document, but for what it is there it is.

18

19

20

21

22

23

24

25

A. I apologize, he was in China and we got this done, I see some typos here and it is very embarrassing, but the facts I think are pretty straight.

Q. Doctor, there are just a couple of other, two other patients about whom I wanted to ask you the basis for the conclusion that the death was not unexpected. First, John Onofre, he is Code No. 15 and he is found at page 105 of the binder. Again I tell you, Doctor, so there will be nothing disclosed, this is a child about whom there has



1
2 been a difference of opinion in the evidence that
3 we have heard here so far. It is clear which side
4 of the line your team came down upon, and I would
5 like to know please, if you can, the basis upon
6 which it formed the conclusion that death was not
7 unexpected?

8 A. I have been looking through
9 this, we don't seem to have the record report on
10 Onofre from the EKG. I wonder if this is one of the
11 charts we didn't have the zebra chart on, I am not
12 sure I will have to - I didn't see this in this
document.

13 In this particular patient again you
14 had a patient who had a serious disease but from our
15 review here this patient was showing very irregular
16 abnormal heart beats from November 25th up until
17 December the 9th when the patient expired. So you
18 had about two weeks of abnormal rhythms which were
19 associated, as it turned out, with administration
20 of digitalis, and presumably in amounts that were
21 felt to be therapeutic and the patient had a sudden
fall in heart rate and died.

22 Now I think that the feeling here
23 was, as I recall the debate, that we had no evidence
24 of digitalis intoxication during the course of the
25



1
2 patient's illness other than this designation that
3 there was an irregular heart beat. One of the
4 things that was confusing here, particularly with
5 Onofre, was the fact that the digitalis which had
6 been stopped on the 4th of December, and to the
7 best of our knowledge I think had not been started
8 up again in the last five days of that patient's
9 life, yet irregularities in heart rate did exist
and the reason for this was never clear to us.

10 I suppose now in looking through this
11 particular one, here again there is great uncertainty
12 in my mind as to what the cause of death was here
13 and I am almost tempted to put this into the category
of unanticipated.

14 Now the reason I'm being so flexible
15 on this particular one is that at least as far as I
16 can see from the summary sheet, the only issue in
17 my mind here was whether or not the irregular heart
18 beat that we saw in this patient was due to the
19 digitalis, and I suppose what I would like to do is
20 review that chart perhaps at the break and offer an
opinion on that again.

21 Q. Certainly, Doctor, I think
22 it will be helpful if you do that. Perhaps I should
23 tell you in that context that it was Dr. Rowe's
24
25



1
2 evidence here that the death of this child surprised
3 him at the time, but that his surprise disappeared
4 after he saw the autopsy report. Perhaps during
5 the break you will have an opportunity to look at
6 the autopsy report and see if that helps resolve
7 the question as to whether his death was unexpected
8 in light of the child's condition.

9 A. This patient didn't have a
10 traditional tetralogy of Fallot, this patient only
11 had three or four other associated defects, and again
12 it comes up to a judgment on this. I am not at all
13 certain - I know we will not have unanimity of opinion
14 on it, the kind of enlightenment that I can provide
15 I am not certain about. This patient again was obviously
16 at risk because the patient had really not responded
17 well in my understanding to the perceived Taussig
18 procedure, but let me review the chart if I may, this
19 is sketchy in here.

20 Q. Perhaps you will do that.
21 Perhaps this is an appropriate time Mr. Commissioner.

22 THE COMMISSIONER: Yes, all right,
23 20 minutes.
24
25



H:
BM:
yk

1

2

--- Upon Resuming.

3

THE COMMISSIONER: Yes, Mr. Lamek.

4

MR. LAMEK: Thank you, sir. Dr.

5

Mirkin, when we broke you were going to review the chart of John Onofre to see if you could help us with the basis for the view that the death was not unexpected. Were you able to find anything in the chart which helps you?

6

7

8

9

A. Yes. I found several things here that are not inconsistent with the serious nature of this patient's illness. In the path report --

10

11

12

O. I am sorry, could you direct me to the page?

13

14

15

A. I beg your pardon. This is page 33. No, it is not in your document this is John Onofre's chart.

16

17

Q. Yes, medical chart.

A. Medical chart, page 33.

18

19

20

21

22

23

24

25

There are some descriptions of the very, very complicated congenital heart disease that this patient had. There are three or four or five major abnormalities. Now, one of the other things that was present here is the fact that there was some infracts in the brain and whether or not some secondary process was on-going is hard to say or



H2

1

2

3

4

5

6

7

8

9

10

11

12

13

14

15

16

17

18

19

20

21

22

23

24

25

whether these are terminal events, agonal events is difficult to interpret. But I think that even though in here it says death in this case was somewhat sudden and unexpected being manifest by sudden onset of bradycardia and cardiac arrest, I think that is really the basis for the unexpected nature statement and I think though that my feeling was that the arrhythmia or an infection could have easily explained this particular patient's problem. This is a very sick baby and I would not buy the unexpected nature of this one.

Q. Okay. Thank you for that, Doctor.

Finally on this list of unasterisked children could I ask you please to look at your Code No.9 Gage found at page 37 of the binder. Can you tell us please the basis upon which it was decided by your team that that child's death was not unexpected?

A. Well, here again we had a patient with a very very complicated congenital disease and the patient had been cyanotic all along, did not have a very good response to the surgery. So, the oxygen saturation was extremely poor. During the last week of life this patient began to



H3

1
2 have progressive heart failure and vomiting.

3 Now, the vomiting might have been
4 consistent with digitalis intoxication and that of
5 course again as you have heard over these past months
6 is sometimes difficult to ascertain. We felt that
7 here was a patient who was just refractory to
8 therapy, had not responded well to the surgical
9 intervention and was just going downhill.

10 Q. Thank you.

11 A. I think this is worth
12 mentioning that we did also feel there was some
13 evidence here for digitalis intoxication during the
14 course of this patient's life.

15 Q. During his life?

16 A. Yes.

17 Q. Can we just look at the other
18 side of the ledger for a couple of minutes, Doctor.
19 Your team has marked two names with an asterisk and
20 as being unexpected deaths and I would like to know
21 please the basis upon which that conclusion was
22 reached. The first is your Code No.12, Adamo, and
23 his data sheet is found at page 5 of the binder.

24 A. Adamo was an interesting
25 patient who died four days of age and this patient
had had transposition of great vessels, pulomony
stenosis and dextrocardia. The patient also had a



H4

1
2 surgical procedure and seemed to be fairly stable as
3 best as we could interpret from the record and
4 following instrumentation with a nasal gastric tube,
5 which is simply a plastic tube that is inserted
6 down into the stomach, this patient had a cardiac
7 arrest and expired. Now, we just attributed this
8 to an instrumentation death. Now, admittedly it is
9 unusual but they do occur - I should say we put it
10 in the unanticipated range because it is an unusual
11 event but I would like to emphasize that this does
12 occur and has been documented in the record.

12 Q. Did your team form a view,
13 Dr. Mirkin as to whether this child's clinical
14 condition was such that his death could have occurred
15 at any time?

15 A. I don't think we formed an
16 opinion on that. I don't see any notation to that
17 event but I do think it is worth noting that
18 following a catheterization study on October 15th
19 this patient became progressively worse, developed
20 a very rapid heart rate and rapid respirations on
21 the 17th, following the operative procedure on the
22 18th, needed intravenous therapy and digitalis
23 was started and on the 19th the baby expired.
24 So, we felt that, I would say, normally this baby would
25



H5

1

2

3

4

5

6

7

8

9

10

11

12

13

14

15

16

17

18

19

20

21

22

23

24

25

have been anticipated to live. I think I will say that we did reach a conclusion that we would have expected this infant to have lived and that this death was unexpected following simple insertion of a nasal gastric tube.

Did I confuse you?

Q. Well, I want to understand exactly what it is you are saying, Doctor.

Are you saying that his death at the time that it occurred, and can we put aside for the moment the occasion of its occurrence, that is to say the insertion of the NG tube?

A. Yes.

Q. Let's put aside the occasion of its occurrence. Are you saying that his death at the time that it occurred was not consistent with his clinical condition and course?

A. I think so, yes. I think I would say that and that is why it is asterisked. We assumed that the death was due to the instrumentation, which was the only documented event that had occurred between the time of death and his prior condition which was, if not highly satisfactory, stable.

Q. Okay. But it is your assessment, if I understand you then, that this child's



1
2 condition was not so precarious that his death could
3 be triggered by the mere insertion of a nasal gastric
4 tube, or you would not expect it to be?

5 A. You would not expect it I
6 think.

7 Q. Okay, thank you.

8 Finally, your No.22, Fazio, and that
9 is found at page 29 of the binder. On what basis do
10 you regard the Fazio child's death as being unexpected?

11 A. Well, first off we found this
12 patient had a coarctation of the aorta which is
13 normally very amenable to the treatment. On March
14 11th this patient was described as being in no
15 apparent distress and tolerating feedings. On March
16 12th, this is one day before death, the heart rate
17 increased, the baby went into congestive failure,
18 on March 13th the day of death the baby developed
19 slow heart rate and was unable to be resuscitated.
20 We have a pre mortem blood level of digoxin on
21 March 12th, which is 2.6. We have really no data
22 showing digitalis arrhythmias.

23 Q. I'm sorry, are we talking
24 about Frank Fazio?

25 A. Oops, sorry, I pulled the
wrong chart out.



1

2

3

4

5

6

7

8

9

10

11

12

13

14

15

16

17

18

19

20

21

22

23

24

25

Q. Yes, I couldn't find those levels either.

A. I am terribly sorry, you had better strike that, I was reading Kristin Inwood.

Q. Yes.

A. All right.

Q. It didn't sound familiar as being Fazio I confess.

A. I guess it didn't to me either. What number is Fazio again?

Q. Here's your number, I think it is 12.

MS. CRONK: 22, page 29.

MR. LAMEK: 22, I'm sorry.

THE WITNESS: Yes, okay, let me get that out.

Q. You have marked it as an unexpected death in view of your team?

A. Yes, here we are. This patient also had coarctation of the aorta?

Q. That's correct.

A. I'm sorry, that is probably what confused me on this. This patient had a hospitalization which went on roughly about one month and on February 3rd, 1981, the patient was described



1
2 as being considerably improved. The next day,
3 February 4th, the patient developed a very slow
4 heart rate and ventricular fibrillation. We did
5 have some serum digoxin levels during the course
6 of this hospitalization which indicated they were
7 in a normal range or a therapeutic range one that would
8 not be consistent with a diagnosis of digitoxication.



1

10jan84

2

I

DPrC

3

4

5

6

7

8

9

10

11

12

13

14

15

16

17

18

19

20

21

22

23

24

25

It was clear, though, that the patient was in heart failure and this developed very acutely. We really could not understand the development of that. One could speculate that this might have been due to a digitalis-induced event. It certainly is consistent with that process, but we have no data to confirm that.

Q. Was it the view of your team that the death of this child and the time that it occurred was not consistent with his clinical course and condition, as disclosed in the chart?

A. Yes. We felt that it was not.

Q. What do you make of the sepsis, as diagnosed in the child, the septicemia?

A. The fact that it was there. These illnesses can be life-threatening in a one-month-old baby but the concern that we had was on the day before death the baby is described as being improved and stable, which made us feel that the sudden occurrence of the bradycardia and the ventricular fibrillation was very odd.

Q. Do you have the chart available to you at the moment, Dr. Mirkin? I think we should just take a moment --



I2

1

2

A. No, I don't.

3

4

5

6

7

8

9

10

11

12

Q. I have to say that the opinion that your team is expressing is at variance with that that we have heard so far, and I wanted to explore it just a little with you.

Could we turn to page 70 of the chart, which is part of the progress notes, the nursing notes. You will find there a note under the date of February 3, 1981, which was the day before the night upon which the child died:

"Sepsis, blood cultures from..." whatever those things may be.

13

14

15

16

17

The nursing note on the following page for the same day records, in the vital signs, "he seems much more stable today", but also records "episodes of tachycardia; apex 150-160, except above 200 on the monitor, twice, and auscultation 180 but heart rate regular".

18

19

20

21

22

23

24

25

The evidence that we have heard from other physicians, doctor, is that this child's death at this time was consistent with his clinical condition, and I take it that, in arriving at a different conclusion, your team considered the evidence of sepsis on the day preceding his death and the variable heart rates that were recorded on



I3

1

2

that day?

3

4

5

6

A. Yes. I think, in order to entertain a diagnosis of death attributable to the infection - which is, I believe, what you are inferring --

7

8

9

10

11

Q. I am not inferring it; I am just putting the picture there.

A. -- which, I believe, is perhaps what the other consultants have used for their decision-making - one must look at a variety of factors here.

12

13

14

15

16

17

18

19

20

21

22

23

24

25

We have here the nursing notes suggesting that the patient was "much more stable today"; we have the patient here with a temperature that is reasonably stable; you have a heart rate of 150 that, in a one-month-old infant, would not be considered unusual - it did go up some, up and down. It says that the heart rate "is regular", which is important. We have here that respiration was "much improved today". At the bottom of that note, you will note that the patient was described as "sleeping well and having decreased irritability" and, very significantly, the blood pressure in this patient is in a relatively normal range.

I think that, when you are going



I4 1
2 to describe an individual with sepsis, let us say,
3 the death that occurs in a newborn infant, the
4 blood pressure falls; they go into shock, essentially,
5 and this particular description is totally in-
6 consistent with that, in my opinion.

7 So, based on that, I would have
8 concluded that this patient, on the day before its
9 demise, was considered stable, and I think that is
10 the premise on which we operated, from the notes.

11 I hope that clarifies the
12 decision-making process.

13 Q. In the light of that, the
14 sudden decline in the early hours of the morning
15 of the 4th was, in your view, unexpected?

16 A. Yes.

17 Q. Believe me, Dr. Mirkin, I
18 am not interested in uniformity so much as in under-
19 standing the reasons for the differences.

20 In your final scoring of these
21 children, you produce six with a probability rating
22 of greater than 7, and we now understand what that
23 means. It means that, at some time in the life of
24 these children, there was evidence that has led you
25 to conclude that they had probably been suffering
from digoxin toxicity.



I5

1

2

3

4

5

6

7

8

9

10

11

12

13

14

15

16

17

18

19

20

21

22

23

24

25

Can we turn now to -- perhaps
one other question before I get to that.

Justin Cook is not in that
"likely" category. Justin Cook receives a score of
zero. I am interested in pursuing that for a
moment.

You are aware, I take it, Dr.
Mirkin, that a sample of blood was drawn from Justin
Cook in the course of the resuscitation effort that
was conducted on the morning of the 22nd of March?

A. That is correct.

Q. The arrest was called at
4:20. The sample was apparently drawn at 4:30.
Death was pronounced at 4:56. An assay of that
sample taking during the course of the arrest yielded
a digoxin concentration of 72 nanograms.

You are aware, I take it, of the
symptoms of the child exhibited at the time of the
arrest; arryhtymias, bradycardia, ventricular
fibrillation, generalized seizure; that sort of
thing.

Putting together the 72 nanogram
concentration in the sample taken at 4:30 in the
morning with those symptoms, can you explain to me
why there is no basis - as I assume there is not in



I6

1

2

3

4

5

6

7

8

9

10

11

12

13

14

15

16

17

18

19

20

21

22

23

24

25

the view of your team - for considering Justin Cook to have been suffering from digoxin intoxication prior to the time when he was pronounced dead?

A. I thought you were going to ask a different question; why was this not an unanticipated death.

Q. No.

A. Okay. Let us go back to the first one.

Q. In terms of it not being an unanticipated death, I say to you, doctor, that you are at one with all the others who say, look, this clinical condition of this child could have led him to die at any time.

I am not concerned about that. I am concerned about what I call technically an ante mortem blood sample with a very high digoxin concentration and sepsis, which, as I understand the evidence we have heard here, are consistent with digoxin toxicity - all those occurring prior to the pronouncement of death and, yet, your team's conclusion is that there is no evidence at any time in the course of this child's hospitalization to suggest digoxin intoxication.

A. Well, we are not at such variance as it seems. I think I reviewed this



I7

1

2

particular patient.

3

Q. Yes.

4

5

6

7

8

9

10

11

12

13

14

15

16

17

18

19

20

21

22

23

24

25

A. The discrepancy, I would say,

is a technical one because, in the charts, we have

a blood sample that was drawn for digoxin serum level

measurement that, at the time I reviewed the chart,

I was unable to discern whether it was pre mortem or

post mortem. I assumed that this was a post mortem

level of 72 and, since the hour of death was

described as 0500 and the sample was drawn presumably

at 0430, I should have known that this was a half

hour before death. Nonetheless, that was the premise

on which I was operating. So that we assumed that

this patient's death was certainly compatible with

a high concentration of -- certainly compatible

with digitalis intoxication or attributable to it,

most likely.

If one assumes that this is a

pre mortem blood level, then one must conclude that

this patient was exhibiting -- the signs and symptoms

that this patient showed at the time of death were

attributable to this and, therefore, one would say

this patient had digitalis intoxication at the time

preceding death.

So, I think it is more of a technical



I8

1

2

distinction.

3

4

5

Q. It simply reflects what,
an uncertainty as to whether the 72 level was recorded
in an ante or post mortem sample?

6

A. Correct.

7

8

9

10

11

I think, if the data, in reviewing
this again, if those time points are actually precise,
and I conclude they might be, or it is not certain
but, if they are precise, then I think we can switch
this to a rating of 9, based on that technical
distinction.

12

13

14

Q. Dr. Mirkin, that, I think,
leads us to what is not in your memorandum report
but what is, frankly, the question with which we are
particularly concerned.

15

16

17

18

19

20

Of the 36 children whose charts and
Zebra packs were available, whose ante mortem and
post mortem serum and tissue level digoxin concentra-
tions you considered, were there some whom you con-
cluded that digoxin intoxication probably caused
or contributed to their deaths?

21

A. Yes, there were.

22

Q. Can you tell me which they
were, please?

23

24

25

A. I have numbered these in
descending order.



J
DM/PS

1

2

My Code No. 35 is Allana Miller.

3

4

5

Q. I'm sorry, when you say in descending order you mean in descending order of probability?

6

A. No, in descending order of recording.

7

8

Q. In the chart?

9

10

A. Descending order of reporting.
I am sorry, go ahead, I am just going from the highest code number down.

11

Q. All right, thank you.

12

A. To give you some trend of the way my mind works.

13

14

Q. All right.

15

16

A. I didn't think you would find that so amusing. No. 35 Allana Miller; No. 34, Justin Cook; No. 30, Kevin Pascai.

17

18

Q. Indeed, that is spelled as Pascai but indeed it is Pacsai. Yes?

19

20

21

22

A. Now, those were cases where we felt digitalis intoxication was very involved here and which was also clearly defined by specific data that was available, or confirmed in our view by some of the data that was available.

23

24

25

Q. Yes.



1
2 A. There was another group of
3 patients in whom we felt the demise of the patient
4 could conceivably have been associated with potassium
5 and one of the patients was Kristin Inwood, No. 32,
6 and we can review that.

7 There is also a patient group in
8 which no digitalis was apparently recorded as having
9 been given and post mortem analysis showed that these
10 patients had elevated amounts, which in our opinion
11 we thought could have been consistent with the demise
12 of the patient. These are No. 28, Jordan Hines; No. 18, J
13 Belanger; No. 17, Stephanie Lombardo. I think
14 we have heard, or have just heard that with Estrella
15 the data base on which we originally evaluated her
16 may be open to some question. Even though it was
17 clear that No. 21, Estrella, did have clear signs of
18 digitalis intoxication during the course of her
19 illness, we are not sure and I would like to with-
20 hold judgment on that particular case until I
21 review this again, perhaps this afternoon, I want
22 to go over some points.

23 Q. True enough. It is,
24 Doctor, that I told you just this morning the evidence
25 has been given here about the sample taken from
Janice Estrella following autopsy in which a level of



1
2 72 nanograms was reached. Prior to that, had
3 Estrella been in any of the groups, either the
4 first or third group of patients that you referred
5 me to; the first group being Miller, Cook and
6 Pacsai in which you concluded that digoxin was
7 very probably involved in the death, was she in that
8 group or was she in the Hines, Belanger, Lombardo
9 group where you concluded there was possible digoxin
involvement?

10 A. This patient had very
11 significant disease, if I may go back a minute?

12 Q. Yes.

13 A. ...that confused the interpreta-
14 tion to some extent. We felt this patient did have
15 very clear evidence of digitalis intoxication.
16 We did not at the time feel that this patient's
17 death was unexpected, and the reason for that was
18 based on her -- well, I would say poor condition and
19 I think the fact that she had some generally, some
20 general genetic, she was a trisomy-21. So
21 I don't think anyone here was willing to note,
22 as I recall my notes, that this was an unanticipated
23 death. I am a little -- at this point we have just
24 the evidence here that this patient had severe
25 electrocardiographic anomalies that we attributed to



1
2 the digitalis and we felt that this patient had
3 some data there showing elevated blood levels.
4 Even during the time she was under treatment she
5 had blood levels of 4.7, which would be consistent,
6 by most people, would be thought to be in the toxic
7 range for this age group. So you have evidence here
8 of a patient with digitalis intoxication and it was
9 impossible I think for us to attribute that the
10 death was due to the digitalis intoxication,
11 although she did have it, I think, up until the
12 time of her death.

13 Q. Dr. Mirkin, what did you make
14 of that 72 nanogram level that was reported?

15 A. Okay. When we had the 72 we
16 concluded at the time not knowing anything about
17 the validity of that data, that this patient would
18 fall, actually should have fallen into a category
19 with the first three. Okay, I'm sorry, I misunder-
20 stood your point.

21 Q. And obviously that would have
22 to be reassessed in light of what you now know about
23 the questionable validity of the sample in which that
24 72 level was recorded.

25 A. Yes. The reason I went into
the previous detail here was that there was evidence



1

2

prior to the death of the patient.

3

Q. Yes.

4

5

6

7

8

A. That the digitalis intoxication was present and that is one of the reasons we reviewed it. There was also evidence that there were higher than normal levels there, not in the range of 72, but they were higher than what would have been desirable perhaps for this patient.

9

10

11

12

13

14

15

16

17

Q. As you can imagine, Dr. Mirkin, we have heard a good deal about the Cook and Miller cases and as to the bases upon which different people have come to the conclusion that those children probably died of digoxin intoxication. Can you summarize for us briefly, Doctor, if possible, the basis upon which you concluded that Cook first, and subsequently Miller, probably died as a result of some digoxin intoxication involvement?

18

19

THE COMMISSIONER: Did you deliberately ask just for Miller and Cook?

20

21

22

MR. LAMEK: Yes, because there is a special question with respect to Pacsai in light of what Dr. Mirkin said earlier.

23

24

25

A. Well I think the circumstances surrounding the last two days of life of



1

2

this patient are suggestive of this conclusion.

3

Q. I'm sorry, you are now talking

4

about?

5

A. Justin Cook.

6

Q. Justin Cook, thank you.

Yes?

7

A. Justin Cook you may recall,

8

on March 21st following admission the previous day

9

on March 20th, had successfully completed his

10

cardiac catheterization. At about 6:30 that

11

evening, this is the 21st, this patient developed

12

a tetrad spell, that is became cyanotic, that

13

did respond to treatment. The next morning,

14

March 22nd, this is roughly 6-7 hours after the

15

first, the patient had another spell that did not --

16

well, I have a note here that following this dose of

17

propranolol for treatment, this is on the second

18

spell, the heart rate fell down, the patient was

19

given atropin and morphine and did well after

this. Now, the notes were not legible in my copy.

20

Q. Perhaps we should have a look

21

at them, Doctor.

22

A. Yes. I have received some

23

additional information suggesting that the patient

24

did not respond to the second dose correctly, is that

25



1

2

your understanding?

3

4

5

6

7

8

9

10

11

12

13

14

15

16

17

18

19

20

21

22

23

24

25

Q. I think the chart discloses, Dr. Mirkin, that he did not respond to either of two doses of propranolol given in rapid succession, but did show a good response to the atropin.

A. The atropin, that is what I am referring to, yes. Okay. So what I have is a correct interpretation.

Q. A good, but I should say, not a sustained response to it.

A. It wasn't sustained because this patient died very shortly thereafter.

Q. That is right.

A. I think the important point here is that the treatment of this disease symptom complex is generally managed by the use of propranolol to slow the heart rate and to allow oxygenation to occur.

Q. I'm sorry, you have been given the wrong chart. Could we have Cook, please?

THE COMMISSIONER: I'm sorry, it is my fault.

Q. You have the wrong chart.

A. Thank you. Well, to just go back over this a bit.



1

2

Q. Yes.

3

A. The first tetrad spell

4

responded very well to the propranolol, the second

5

did not respond well to the propranolol, but the

6

patient's heart rate slowed to about 80. The

7

patient was then given atropin which presumably

8

will counteract the effect of the propranolol slightly

9

and the patient appeared to be stable thereafter.

10

Following which the patient had developed ventricular

11

fibrillation and failed to respond after active

12

aggressive resuscitation. This particular patient

13

had very clear evidence in our opinion at the time

14

of death that there might have been some suggestion

15

of dig. intoxication. Now, we, as you have noticed,

16

have given this a rating of zero. So during the time

17

that this patient was alive, in our opinion, not

18

knowing the post mortem or at the time presumed

19

post mortem level of 72, we did not consider this

patient to have had any signs of digitalis intoxica-

tion.

20

Taking this now and identifying the

21

0430 blood level as an ante mortem blood level, one

22

then can reconstruct these scenarios somewhat

23

differently. Looking at the findings here we have

24

a picture which is completely compatible in my opinion

25



1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25

with digitalis overdose.

Q. You say completely compatible,
are you prepared to be any stronger than that?
Can I suggest a number of things to you, perhaps,
Doctor, to see if mere compatibility is as far as
you are prepared to go; if it is, I am content, of
course. You have a concentration of 72 nanograms
in the sample taken ten minutes after arrest and
30 minutes before death is pronounced. You have
post mortem concentrations which are certainly
consistent with that level. You have concentrations
in fresh tissue of actually 1200 nanograms per gram
in heart tissue, and I have forgotten the number in
lung. You have the symptoms displayed by this
child prior to arrest.



K:
BM:
yk

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25

In those circumstances is the death of the child, the arrest of the child no more than compatible with digoxin intoxication, recognizing too that this was a child for whom digoxin was never prescribed?

A. Yes, I think the latter point really has no bearing on the conclusion that is reached.

Q. All right.

A. Because that essentially deals in my opinion with the maliciousness or the appropriateness of the treatment. I think though that the observations that you reported certainly are compatible, highly suggestive of digitalis intoxication. Whether one wants to go and say with absolute certainty a patient with a blood level of 72 would show digitalis intoxication I don't think you can go that far but if we are going to give a number to it it is probably 90 per cent probable that that kind of blood level which produce some significant adverse effect in the patient. I think I would go that far. The sense of certainty, I think it is improper to say that at all times that this would occur.

Q. Okay.

A. Or incorrect, factually



K2

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25

incorrect.

Q. I acknowledge that certainty doesn't exist in this area. Is it your view, Dr. Mirkin, that digoxin intoxication was probably the cause of this child's death?

A. Yes, it is certainly our opinion on that.

Q. All right. Now, I want to come back to other aspects of that in a moment but can we move on to Miller. Let me ask you first the question that I have just asked you with respect to Justin Cook. Is it your view that digoxin intoxication was probably the cause of Allana Miller's death?

A. Yes.

Q. Thank you. And what are the factors that you take into consideration in forming that opinion?

A. Well, at the time of death of this patient, March 21st - it just struck me that the time frame was so similar in these two patients, I wasn't aware of that.

Q. Right.

A. I guess everyone else is. This patient presented with a very severe bradycardia,





K3

1

2

3

4

5

6

7

8

9

10

11

12

13

14

15

16

17

18

19

20

21

22

23

24

25

slowing of heart rate and heart stop. At the time and even prior to that, this patient had not really been demonstrating much evidence of digitalis intoxication. A blood level taken on March 19th was 0.6 nanograms per mil. in this patient. The post mortem level that we have is greater than 78, is that correct?

Q. I think 78.

A. 78.

Q. Yes.

A. And we felt that these findings were certainly compatible again with the diagnosis of digitalis induced arrhythmias and death.

Q. I take it Doctor from the answer to the question that I asked you a couple of minutes ago, that is to say it is your view that the child's death was probably caused by digoxin intoxication that it is also your view that the events you have described and the situation you have described is rather more than merely compatible with digoxin intoxication?

A. Yes, they are entirely consistent with it.

Q. It is at least consistent



K4

1

2

3

4

and in your view I take it rather more - digoxin
intoxication probably existed and caused the death
of the child.

5

6

7

A. Well, Mr. Lamek, I'm not
sure what can be more descriptive than consistent
with something; more consistent, less consistent?

8

9

Q. Okay, your earlier answer
I think is the one that interests me.

10

11

12

13

14

15

16

17

18

19

20

21

22

23

24

25

THE COMMISSIONER: Well, no,
unfortunately though, Doctor, almost all of these
children, the events, the terminal events were
consistent with digoxin intoxication. The real
question that we are asking though is, in your opinion,
taking the terminal events, taking the clinical
symptoms, the clinical condition of the child, the
digoxin readings, digoxin levels taken after death
in this case, before death in some, it is your
opinion the child died of digoxin intoxication, that's
the question. We start off that they are all, almost
all consistent. There may be one or two that are
not too consistent and those we have ceased to inquire
into some time ago, perhaps not formally, but most of
the others of the 36 I would say, at least 30 of
them, are consistent with digoxin intoxication because
that is consistent with many other types of manners of



K5

1

2

3

4

5

6

7

8

9

10

11

12

13

14

15

16

17

18

19

20

21

22

23

24

25

death in these children who died from their clinical symptoms, they could die from the digoxin intoxication. We want your help. What is your view as to which - if you help us you can also tell us why you think that. That was all prompted by your saying that you can't be any higher than being consistent. Well, if you can't be any higher than being consistent then all of these children are consistent with digoxin intoxication and so are a lot of other children who died with no digoxin anywhere near them.

THE WITNESS: Well, I would take exception with your statement that 36 of these patients had findings consistent with digoxin intoxication.

THE COMMISSIONER: Well, can you help us on that then. I would be grateful if you would give me those that are inconsistent with digoxin intoxication, that would help.

THE WITNESS: I think that is what we tried to develop with this scoring system, Mr. Grange. I think the question posed to me is clear now. Consistent with is different from requesting a statement regarding whether digoxin was responsible for the death of these individuals. I would say that is a different dimension and I think I felt with Cook that



1

K6

2

this was correct, that this patient did die from the digitalis intoxication. I think, based on what we see here with Allana Miller, I would be prepared to say the same, I am saying the same.

5

6

THE COMMISSIONER: Yes, and I think you said the same for Pacsai too?

7

8

THE WITNESS: I don't know what I said.

9

10

THE COMMISSIONER: And with Inwood except for the potassium problem and Belanger and Lombardo also.

11

12

THE WITNESS: Okay.

13

14

15

16

17

THE COMMISSIONER: But are there not any others - are there many others where the death is consistent with the digixon intoxication but where perhaps for some reason you don't believe that that was the effective cause of death, or indeed any cause of death?

18

19

20

THE WITNESS: I think all of the patients that we thought died as a consequence of digitalis administration have been noted.

21

22

THE COMMISSIONER: Are those all of those over seven would you say?

23

24

25

MR. LAMEK: No, no.

THE WITNESS: No, I want to - if that's



1
K7 2 the way this is being interpreted then I think we
3 must go over that point again.

4 THE COMMISSIONER: It's not a point
5 of being interpreted, I think the problem is ---

6 THE WITNESS: The scoring.

7 THE COMMISSIONER: Oh, the scoring?

8 THE WITNESS: Yes, I'm sorry.

9 THE COMMISSIONER: Yes, all right.

10 THE WITNESS: If I may, the score
11 really does not relate, as we mentioned earlier, to
12 the --

13 THE COMMISSIONER: Cause of death.

14 THE WITNESS: -- involvement of
15 digitalis intoxication as a cause of death.

16 THE COMMISSIONER: No.

17 THE WITNESS: Okay, I think that is
18 clear, I'm sure you follow that now.

19 THE COMMISSIONER: Yes.

20 THE WITNESS: Now, we believe that
21 these patients with high score showed some effect
22 from digitalis being given at some time during the
23 course of their management. So, as you can see from
24 the 36 here we had, oh, I think there were six in
25 which we graded an effect that would be consistent
with digitalis intoxication based on the available



K8

1

2

data and there was one that was more ambiguous, No.27
with a scoring of 5.5.

4

5

6

7

8

9

10

11

12

THE COMMISSIONER: But you can't,
you see, the trouble with your scoring, and I under-
stand that there seems to have been some difficulty
of course but clearly in all of these cases, take
Lombardo, take Belanger, take Cook, Miller, Inwood,
all of these ones that others considered very
suspicious, you have a score of zero. That doesn't
mean that the events of their death were not consistent
with digoxin intoxication, you have just told us that
with Miller and Cook you think they died of that.

13

14

THE WITNESS: That is a perfectly
correct interpretation.

15

16

17

18

19

20

21

22

23

24

25

THE COMMISSIONER: So, what I would
like to know from you, if it is possible, and you
don't have to if you don't feel that you are qualified,
is those that were consistent, that is, the terminal
events that were consistent with digoxin intoxication
and if that is as far as you can go, that's fine, if
you can also go as far as to say that notwithstanding
that I don't think they died of digoxin intoxication
that might help, or if you can say I do think that
they died or you can give them some kind of rating,
that would help.



K9

1

2

3

4

5

6

7

8

9

10

11

12

13

14

15

16

17

18

19

20

21

22

23

24

25

Now, I don't know whether you can,
I don't know whether you have attacked this problem
that way.

THE WITNESS: No, I think we have
thought about it in that context but the precision
of the judgment is dependent on the data available.

THE COMMISSIONER: Unfortunately I
am required to give an answer and even though the
precision of the details may not be there I've
got to give it. So, I've got to get whatever help I
can. So, if you can, if you can.

THE WITNESS: Is that correct, Mr.
Grange, that only justice is blind?

THE COMMISSIONER: Well, I don't know
that we are even discussing justice at this moment.

THE WITNESS: We're not.

THE COMMISSIONER: This is an inquiry
and I have to give an answer and I want some help.
The trouble is I know that both medicine and the law
are not precise sciences but I have to do the best
I can and you are the expert and therefore I am asking
you for your assistance. There is no reason why you
can't give an opinion and if you can give it, basing
it on some well thought out process, you can be wrong
and I won't hold it against you and I may even adopt
your wrongness as my own. Do you understand? Do



K10

1

2

3

4

5

6

7

8

9

10

11

12

13

14

15

16

17

18

19

20

21

22

23

24

25

you understand what we're doing? We're not playing God, we can't play God, we don't know how but we can get the best answer that we can get.

Now, there is no question that your scoring of zero or nine doesn't help us as to whether the child died of that disease or not because the child could have a 9 and could recover completely from the digoxin and go ahead and die from something else. On the other hand, the child could have a zero and, as you have said, in the case of Cook and Miller, notwithstanding that zero throughout the life you believe they died of digoxin intoxication.

Now, can you help us on the issue we are really at here, which is, which one of these children in your opinion, looking at the chart and toxicology and anything else that you want to look at, you believe died of digoxin intoxication.

I am putting in time until 1 o'clock so that if you want to we can retire and you can think about that and see if you can give an answer but it doesn't answer if you say they were consistent with digoxin intoxication because in my view, or at least I had always understood that almost all of these children the terminal events were, and if you can give me some that you think the terminal



K11

1

2

3

4

5

6

7

8

9

10

11

12

13

14

15

16

17

18

19

20

21

22

23

24

25

events were not consistent with digoxin intoxication that will help me to rule out that as a cause of death for those children.

Do you understand? The problem is you don't have to do it. You can only do what you feel you are qualified to do but if you can do it it will be of assistance.

Have you something you want to discuss with the witness?

MR. LAMEK: Could I ask Dr. Mirkin this question, Mr. Commissioner.

Q. Dr. Mirkin, as a pharmacologist do you feel able to express an opinion as to the likelihood of digoxin intoxication being involved in the death of a patient if you do not have toxicological data which are indicative of such involvement or negate such involvement. Can you make that determination without the toxicological information is my question?

A. One could make a judgment of that sort but it would have to be qualified by the absence.

Q. Yes.

A. What the absence of that data does to your judgment and to the quality of



1
K12 2 that judgment. So, I can stay here and say that I
3 do believe that in these two patients digitalis was
4 very directly involved with the death of the
5 patients.

6

7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25



1

10jan84 2

L

DPrC 3

4

5

6

7

8

9

10

11

12

13

14

15

16

17

18

19

20

21

22

23

24

25

Now, this is substantiated by certain facts. What you are asking, as I understand it, is whether I could reach the same conclusion had I not been presented with the information showing these extraordinarily high levels. I certainly could come down with a somewhat similar conclusion with the restriction or the weakening of that position due to the fact that I don't have toxicological data confirming it. I think that is the problem here.

Certainly, to give an opinion, I have not been known for my lack of temerity in my life - is that backwards - lack of temerity - figure it out.

Q. I think I know what you mean.

A. I'm not sure. Okay.

I think the point here is that it is a decision that I like to make based on the optimum amount of information. I certainly will render some judgments on these cases, as Mr. Grange has requested. I think that is what we are doing. We have already identified Cook and Miller as two patients in whom I feel there is an etiologic relationship between their deaths and the administration of digitalis.



1

L2

2

Q. As I understand it, Dr.

3

Mirkin, the Commissioner would like you to go further than that, if you could - and it may be that you cannot go that far. Believe me, I have known the Commissioner long enough to know that he is not going to clap you in irons because you say, well, in all honesty, I cannot go as far as you would like me to go.

9

10

11

12

13

14

15

16

17

18

The fact is that we have heard evidence here that, focusing solely on the terminal events of these children, the events preceding the arrest, the rapid deterioration that occurred in so many of them, the symptoms displayed by them at, prior to and immediately following arrest and the irreversible and rapid course of the arrest, we have heard that, sure, those events are consistent with digoxin intoxication; they may be consistent with a whole heap of other things as well, but they are consistent with digoxin intoxication.

19

20

21

22

23

24

25

Unhappily, as you know, we do not have toxicological data in most of these cases which enable you to resolve the conundrum, whether those events are truly indicative of digoxin intoxication. It may therefore be, as the Commissioner suggests, that you could be of help to us if you could



L3

1

2

3

4

5

6

7

8

9

10

11

12

13

14

15

16

17

18

19

20

21

22

23

24

25

look at it from the other side and say, can you tell us which of these children died in a way, or with an agonal event, that would lead you to say there is no way that digoxin played a part in these children's deaths; which ones can we put in the 'discard' pile, if you will?

Is it possible for you to do that?

A. Well, I guess we can attempt it. I will have to look at all those charts again to look at that particular --

Q. That would be involved in doing the exercise the Commissioner has in mind:

A. I would have to do that. I am certainly willing to do that. I think I can weed out certain cases here, and we will just undertake that.

Q. That would be a long way from saying those that remained in the pile did have digoxin toxicity involved in their deaths? They may or may not have. We might thus eliminate those who, in your professional view, did not have any digoxin involvement.

Do I put it fairly, Mr. Commissioner?

THE COMMISSIONER: That is right.

If we could have a chart, 1 to 10 - not based on what



L4

1

2

3

4

5

6

7

8

9

10

11

12

13

14

15

16

17

18

19

20

21

22

23

24

25

their symptoms were in the course of life, but on a 1 to 10 basis, with or without -- forget about the toxicological symptoms - 1 to 10. They may all be fine. They may all be consistent with the symptoms of their condition. They may also be consistent with digoxin toxicity in many of the cases - I may be wrong in the 30 out of the 36, but there certainly was a large proportion of them that all of the evidence that we have had so far tells us are consistent with both an anatomical condition and with digoxin intoxication. That is what makes this difficult. Pathology, as you know, there is none, except for the blood readings. There is nothing else that can tell us whether or not the child died with digoxin in its blood or tissues, cannot tell us anything about that. We have done that with some. I remember that I asked if there was no rational finding. I don't think that was Dr. Bain, but it was someone who had a list - was it Dr. Bain?

MS. CRONK: Dr. Fay.

THE COMMISSIONER: That is right.

It was Dr. Fay.

MR. LAMEK: Mr. Commissioner, this is something that perhaps Dr. Mirkin and I can talk about over lunch. It is five minutes to one.



L5

1

2

3

4

5

6

7

8

9

10

11

12

13

14

15

16

17

18

19

20

21

22

23

24

25

THE COMMISSIONER: Yes. Do you want to take a little longer than the ordinary time for lunch?

MR. LAMEK: Mr. Commissioner, why don't we take the usual time for lunch. In any event, even if Dr. Mirkin feels capable of doing it, it is not something that is going to be achieved in the course of even an expanded lunch hour. If Dr. Mirkin feels that he can do something, we can so report to you at the end of lunch, proceed with the matters that we have at hand anyway and then perhaps rise a little early and see what can be done.

THE COMMISSIONER: All right, until 2:30 then.

MR. LAMEK: Thank you.

--- luncheon recess.



1

2

---Upon resuming after the recess.

3

THE COMMISSIONER: Yes, Mr. Lamek.

4

MR. LAMEK: Thank you, sir.

5

Q. Dr. Mirkin, just before we

6

broke for lunch, the Commissioner asked you if

7

you could consider the charts and give him some

8

help with the question, and frame it either from

9

the long end or the short end of the telescope, if

10

you like, as to which of the 36 children show any

11

signs or indications in or about the terminal events

12

which are in your view consistent with digoxin

13

intoxication or, looking at it the other way, which

14

of them shows no signs or indications that are

15

consistent with digoxin intoxication involvement

16

in their deaths, notwithstanding that there may be

17

a lack of pharmacological or toxicological data

18

applicable to the time of death. You undertook with

19

me to discuss that during the course of the lunch

time. Is that an exercise that you feel able to

undertake?

20

A. No, I don't think that I am

21

going to be able to fulfill that request.

22

Q. Perhaps you could just tell

us why you feel unable to do that.

23

A. I think the primary reason is

24

25



1
2 that in many of these situations, I think in most
3 of them, there is insufficient information available
4 to make the kind of judgment that I am qualified
5 to make, one based on pharmacologic and toxicologic
6 data. While I am a clinician, I am not a pediatric
7 cardiologist and would be reluctant to make an
8 observation strictly upon these clinical findings
9 that I do not think I am perfectly qualified to do.

10 Q. Thank you, Dr. Mirkin. You
11 had, however, reverting now to your earlier testimony,
12 you had said of both Cook and Miller that it was your
13 best judgment, on the basis of all of the information
14 available to you, that those two children probably
15 died as a result of digoxin intoxication.

16 A. That is correct.

17 Q. The third child in that
18 group which you identified this morning as comprising
19 those who you judge probably to have died as a
20 result of digoxin intoxication was Pacsai. I
21 wonder if you can tell me, please, upon what
22 information that has been made available that
23 judgment is based.

24 A. Well, to summarize this,
25 the patient began to show signs of digitalis
intoxication at 5:30, the day of his death.



1

2

This patient had definite evidence of digitalis
intoxication, in our opinion.

3

4

Q. What were those signs, please?

5

6

7

8

9

10

11

12

13

14

A. They were major changes in the
electrocardiographic pattern, the rhythm changed,
the heart rate slowed, there was lengthening of the
PR interval. We had evidence suggesting that effects
on the electrical conduction of the heart was
being modified. The digitalis was ordered to be
stopped by the physicians. Three hours later the
patient's heart rate became even slower and there
was complete dissociation of the atrial and ventricular
beats and the patient developed fibrillations and
expired.

15

16

17

18

19

We found that this was paralleled at
the time by laboratory data which indicated there
had been an elevation, a dramatic increase
from a blood level of 1.8 on approximately the 8th
of March to a blood level exceeding 10 on the 11th of
March.

20

21

I don't know if the 26th is the
post mortem --

22

23

24

25

Q. I believe it was the morning
of the 12th, was it not, the greater than 10.

A. It may have been taken on the



1
2 morning of the 12th. I have 3-11, but I can check
3 that in the chart. Then a blood level of 26 was
4 obtained after that.

5 Q. The date on the sample in
6 which the greater than 10 is recorded is at page 83
7 of the chart, Mr. Commissioner, is March 12th.

8 The evidence has been, Doctor,
9 that that was a sample which was drawn for other
10 purposes shortly after the child's admission to the
ICU about 6:00.

11 A. So we have a concurrence
12 of interesting events; one, the abnormality in the
13 electrocardiographic tracing; two, the very
14 precipitous increase in the patient's digitalis
15 concentration which was subsequently confirmed by a
16 third blood level which is at 26. Is that a
post mortem?

17 Q. That is a post mortem.

18 A. So the two key pieces of
19 information here are the increment from 1.8 to
20 greater than 10 in this very brief period. Probably,
21 had the patient been receiving the dosage which was
22 described in the chart, this probably would not have
23 occurred, considering the fact that this patient's
24 renal function was normal at the time these measurements
25



1
2 were made.

3 Q. Doctor, I am interested in that
4 last comment because I rather understood you to say
5 this morning that you assumed the digoxin concentra-
6 tions recorded in this child were consistent with
7 therapeutic administration. That was an assumption
8 you were making. I now understand you to be saying
9 that probably therapeutic administration of the
prescribed doses would not account for these levels.

10 A. I think that under the
11 sequence of events here, when I was speaking this
12 morning I was basing that comment strictly on the
13 premise that the patient was receiving a dose as
14 described in the chart, which is notated in my
15 summary, and if the patient was receiving this
16 particular dose one would not have anticipated this
very sudden increment in the serum concentrations.

17
18
19
20
21
22
23
24
25



BB
DM:
yk

1

2

3

4

5

6

7

8

9

10

11

12

13

14

15

16

17

18

19

20

21

22

23

24

25

At least not under the conditions in which the patient appeared to be. That is to say with the patient with normal renal function one would not have anticipated this dose to reach such a high level. So one must conclude that somehow a greater amount of digoxin was given during this period of time than was actually prescribed in the notes of this patient.

Q. Doctor, the chart of Kevin Pacsai also discloses a marked elevation in serum potassium, do you attach any significance to that in assessing the probable cause of the child's death?

A. Yes. I think I mentioned this morning that certainly death can be attributed to elevations in serum potassium. Quite honestly I don't know the cause for this patient's serum potassium level. I think that it should be noted that patients with serum potassiums of this magnitude 9 and certainly the last one reported was 11.6.

Q. Pacsai? 7 I think, 7.3?

A. I have an 11.6 here, I have 9, 7.7 and I have an 11.6 which perhaps you could confirm for me.

O. That I think to be a post mortem level, Doctor.

A. Okay.



B2

1

2

Q. The last ante mortem --

3

A. These are post mortem

4

Q. The last ante mortem was 7.7.

5

A. Okay.

6

Q. The earlier 9 was in a
hemolyzed sample.

7

8

A. It says 313, so the patient
was - okay, so just to recapitulate for you the serum
potassium concentrations that were reported on the
11th of March were 3.9, and on the 12th of March were
9 and 7.7. Now the latter two are certainly consistent
with causing a reduction in heart rate.

9

10

11

12

13

14

15

Q. I am sorry, could we focus on
the 7.7, Doctor. Perhaps I should ask you first whether
the level recorded in a hemolyzed sample is of any
significance?

16

17

18

19

20

A. Yes. Hemolyzed blood of course
those levels are not an accurate reflection of potassium
in normal serum, because the red cell has large amounts
of potassium and this may spuriously elevate the
level. Were these samples hemolyzed?

21

22

23

24

25

Q. Yes, the 9 sample was
hemolyzed and Dr. Costigan's evidence has been that
report came back to him with a level of 9 with a
notation "hemolyzed sample" and he immediately submitted



1
B3 2 a second sample which produced a 7.7.

3 A. Okay. Now the 7.7 being
4 presumably, or presumptively, I guess the accurate
5 serum potassium in this patient, under those circum-
6 stances I would not have attributed the death of
7 this patient to that elevation in potassium. I
8 think the greater likelihood here is that the digoxin
9 was responsible for causing these arrhythmias and
led to the demise of this patient.

10 Q. Doctor with respect to the
11 three children, Miller, Cook and Pacsai who you placed
12 in that first category and of whom it is your judgment
13 that he probably died as a result of digoxin intoxi-
14 cation. You have read now I think the report of
15 Dr. Kauffman and you have read much of the evidence
of Dr. Spielberg?

16 A. That is correct.

17 Q. And you are aware from that
18 that those two pharmacologists undertook to calculate
19 on the basis of certain assumptions the time and
20 size of dose that may have been administered to each
21 of those children in order to produce the recorded
22 serum levels and you are aware of those calculations.
23 Are those calculations that you have done with respect
to these, or indeed any children of this group?

24 A. No, I decided not to set up
25



B4 1
2 that type of paradigm for the purpose of assessing
3 the potential dose that was given because of a
4 variety of reasons.

5 Q. Can you tell us the major
6 ones please?

7 A. The major reason here is that
8 these are calculations and procedures that we use
9 quite routinely in our patients and in our experimental
10 work, but I felt, and quite strongly, that major
11 assumptions had to be invoked that critically qualified
12 these conclusions. In reviewing what both Dr.
13 Spielberg and Dr. Kauffman have proposed I think given
14 the set of assumptions that they have outlined that
15 their conclusions are reasonable and can be accepted
16 by the Commissioner as adequate estimates of what
17 maximum/minimum amounts of drug could have been given
18 to this patient.

19 Q. Do I take it from that that
20 you regard the assumptions that they made, and they
21 labelled them themselves, as merely - the assumptions
22 they made were in your view reasonable assumptions?

23 A. Yes. I think the premises
24 are accurate and they are based on acceptable
25 knowledge and data in this field.

Q. That is to say assumptions as



1
B5 2 to volume of serum in a child of a given weight; an
3 appropriate selection of volume of distribution for
4 different phases of the distribution curve; a rather
5 key assumption as to the probable route of
6 administration; you considered all those in the case
7 of both Dr. Spielberg and Dr. Kauffman to have been
reasonable assumptions?

8 A. I think I will accept it with-
9 out going to some areas of disagreement. But overall
10 I certainly can accept them. One key factor here
11 is the presumption that the blood level was obtained
12 at a period exceeding five hours after the dosage and
13 I think those are, in addition to the three that you
14 have mentioned, I think that with that fourth one
15 you have the set of criterion that they generally use
16 to come to certain conclusions and I felt that they
were valid in that context.

17 Q. And if you were to engage in
18 the exercise of doing those calculations, labelling
19 the assumptions as such as those two physicians did,
20 I take it the answers that you would come to would be
essentially of the order arrived at by those two?

21 A. Yes pretty much, yes.

22 Q. In that case there is not too
23 much point in duplicating or triplicating the process?
24
25



B6

1

2

3

4

5

6

7

8

9

10

11

12

13

14

15

16

17

18

19

20

21

22

23

24

25

A. Well I think there are certain ones we associated with it. There is also - I am not certain that it will bring further understanding to the proceedings of what may have transpired in these individuals.

Q. Do you share the view both of Dr. Kauffman and Dr. Spielberg that in the case of each of Miller, Cook and Pacsai, the dose of digoxin which in their view as in yours probably caused the death of each child constituted a substantial overdose, given the ranges of gradation there may be in "substantial".

A. Yes. I think the amounts that must have been administered to these patients in order to produce the reported blood levels exceeded those certainly that were reported in the chart which were the therapeutic dosage range. I would have to conclude that the amounts that were given were say of the toxic order or magnitude.

Q. Now, you mentioned four other children in the course of your testimony this morning, one was Kristin Inwood of whom I think you said it was the view of your team that her death was probably attributable to elevated potassium levels, potassium intoxication I take it that would be.



B7

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25

THE COMMISSIONER: That isn't quite what I heard, but you may well be right.

MR. LAMEK: I am sorry.

Q. Perhaps you can remind us what you said this morning, I am sure I have it wrong Dr. Mirkin.

A. What did you hear Mr. Commissioner.

THE COMMISSIONER: I said I had conceivably down here.

MR. LAMEK: Conceivably, I am sorry.

THE WITNESS: Thank you.

THE COMMISSIONER: Conceivably and probably ---

MR. LAMEK: Yes, they are quite different I agree.

Q. If you said conceivably then I do apologize. What was your view when you came in here this morning as to the probable cause of death of Kristin Inwood?

A. Well the truth of the matter is, I don't know. However this particular patient presents somewhat of an enigma. I spoke about the potassium Mr. Lamek because the last recorded potassium level was 7.3, serum potassium in this



1
2 patient, and in lieu of any other cause of death for
3 this patient we were trying to determine why she
4 should have died. This is also complicated, or
5 compounded by the fact that her serum digoxin level
6 was 2.6, that is one day before death, and something
7 I was unaware of was that a sample done post mortem,
8 I missed this in the data, was a level of 491 in some
9 of the cerebal spinal fluid and/or serum combination
10 which now I gather is serum, it has been corrected.

11 Q. Probably serum?

12 A. Probably serum.

13 O. Yes.

14 A. And again the presumptive
15 conclusion to reach based on such a tider would be
16 that even in this patient the death might be associated
17 with the overdose, or this very high level I should
18 say, of digoxin.

19 Q. Were you aware Dr. Mirkin
20 that digoxin concentrations had been measured in
21 the fixed tissue of Kristin Inwood?

22 A. Yes.

23 Q. You had that information did
24 you from Dr. Cimbura's reports. Did you attach any
25 significance to the concentrations of digoxin there
recorded?



1

2

3

A. Well -- In this particular patient?

4

Q. Yes.

5

A. Yes.

6

7

8

Q. Or indeed if you treated this patient as you did any other patient perhaps you had better tell us your overall view of concentrations in fixed tissue.

9

10

11

12

13

14

15

16

17

18

A. I have had great difficulty in dealing with that data particularly attempting to conclude that the presence of digoxin in patients who were receiving the drug as prescribed regimens that these levels provided me at least with any further insight regarding digitalis intoxication. I should add that in those patients who are not officially designated as recipients of digoxin, and in whom the drug was found on post mortem specimens, I regard that as very highly suspicious information.

19

20

Q. We will be coming to those three.

21

A. Yes.

22

23

24

25

Q. Do I take it the thing that has - from what you have said, the thing that has raised the possibility of digoxin involvement in the



1
2 death of Kristin Inwood is the recognition of very
3 high concentrations in what is reported as probably
4 being serum from the child?

5 A. Yes, I think that is correct.
6 In the absence of that - Now there are two alternative
7 conclusions that we were - opposing conclusions I would
8 have reached; one was that this patient in the absence
9 of that information, one was that this patient was
10 not showing signs of digitalis intoxication; that
11 this patient also did not have any real indications
12 clinically of digitalis intoxication that we could
13 discern.

14 In the presence of that information,
15 that is the high post mortem levels, I would have
16 to modify that conclusion and raise the very strong
17 likelihood that if that is in an accurate blood level
18 that this patient's death was associated with the
19 administration of digoxin as well.

20 Q. May we look at the three
21 children who fall into the category to which you have
22 just referred, and whom you placed in that separate
23 category this morning, that is Hines, Belanger and
24 Lombardo, of whom my note is you said that you and
25 your team considered it was possible there had been
some digoxin involvement in their deaths. Can we



1
2 look first at the Hines child. Can you tell me Dr.
3 Mirkin, is that conclusion based on anything other
4 than the finding of what is reported as digoxin in
5 the fixed and subsequently exhumed tissues of the
6 child in light of the consideration that digoxin
7 was not prescribed for him.
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25



1
2 A. Well, I think that there are
3 some clinical observations here that are worth
4 mentioning; one is that to the best of our knowledge
5 this child was suffering with a premortem diagnosis
6 of apnea and bradycardia, developed respiratory arrest
7 and the heart stopped, I am sure you are acquainted
8 with it.

9 We find this not uncommonly in the
10 newborn infants. I think that one of the things
11 that was unusual in this particular patient was
12 that two days after admission this patient developed
13 apnea and went on to develop ventricular tachycardia.
14 Now, most of the situations where you have this,
15 the infants are watched very carefully, they are in
16 intensive care units, the resuscitation is made
17 pretty quickly because of the skill of the nurses.
18 I think it is not terribly common to have these
19 individuals go on to this kind of very profound
20 cardiac arrhythmia.

21 So, that was a very strange thing
22 to see, though, again, one must emphasize, like any-
23 thing else, these can occur as a consequence of the
24 apnea and bradycardia itself. But you also had the
25 situation here where here is a patient with a normal
heart, which was of importance I think in this fact.



1
2 This patient did not have an abnormal myocardium,
3 it was structurally intact as far as we can discern.
4 Furthermore, there was no evidence of digitalis
5 having been given.

6 So, you have some unusual clinical
7 findings here at the time of death. You have the
8 presence of the drug in post mortem specimens which
again raises a high index of suspicion.

9 Q. Now, other than those findings,
10 the observation of certain unusual or unexpected events
11 at or shortly before the time of death and the findings
12 of digoxin in post mortem samples, does anything else
13 contribute to the conclusion that you arrived at
14 that this child was one in whom, as you have just
15 said, there was a high likelihood or reasonable basis
for suspicion or something of that sort?

16 A. No, I think it was just
17 based on those findings.

18 Q. Just on those findings?

19 A. Yes.

20 Q. Thank you. Doctor, are you
21 aware, and indeed I take it you are from the reading
22 of the autopsy report in the chart, that it has been
23 suggested that sudden infant death syndrome was the
24 cause of this child's death. Do you feel qualified to
25



1

2

comment upon that as a diagnosis?

3

4

5

6

7

8

9

10

11

12

13

14

15

16

17

18

19

20

21

22

23

24

25

A. Well, I have no qualifications as a neonatologist, official qualifications. We have carried out many studies in the newborn infant. But I think one thing here is that the child was in an intensive care unit, was under very careful surveillance, is that correct?

Q. No, Hines was on the ward at the time of his death.

A. Ward, okay.

Q. He was attached to both apnea and cardiac monitors, as I recall it.

A. Well, I have here in my notes there was a 15 minute period of apnea. Now, the question comes up --

Q. 15 minutes?

A. Is that correct?

Q. I would be astonished if it were.

A. I would be astonished -- I'm astonished at that also. I just have it in the chart and maybe we ought to look through that one.

Q. I think the units must be wrong, units of time.

A. What is it, 15 seconds? Let's



1

2

hope so.

3

4

5

6

7

8

9

10

11

12

13

14

15

16

17

18

19

20

21

22

23

24

25

Q. Yes, let me find the reference. I have the chart right here. No, I can't put my finger on that reference right now, but I think we may take it that your transcription of it is wrong.

A. It's probably 15 seconds.

Let's hope so.

Q. Yes.

A. I think that most individuals would feel that a baby who was being monitored with a device that would measure respiration, that would not be a 15 minute certainly of apnea. Making that assumption, the development of ventricular tachycardia and fibrillation I consider to be an unusual event in this syndrome. So, I would say that is an unusual finding in my opinion.

Q. Okay. I'm sorry, let me be clear. Do I come to the end of that as your position being that you rather discount the likelihood of sudden infant death syndrome accounting for this child's death? I think that was the question that I asked you.

A. Yes, I think I would minimize that with the disclaimer that I am not an expert in



1

2

the field.

3

4

5

6

7

Q. Yes, okay, understood. Is it your view that the probable cause of this child's death, taking into account the symptoms that you have indicated and the finding of digoxin, the probable cause in your view is digoxin intoxication?

8

A. I think that's reasonable.

10

11

12

13

14

15

Q. Thank you. Now, the other two members of that group were Belanger and Lombardo. Could we look at Belanger first. It was your Code No. 18, and here, Dr. Mirkin, was there anything other than the finding of digoxin in the exhumed tissues of this child which led you and your team to say that this was a death in which the involvement of digoxin intoxication was possible?

16

17

18

19

20

21

22

23

24

25

A. I think that on the day of death -- first of all, this patient had a very, very serious heart problem and one ventricular and had pulmonary stenosis and various valvular abnormalities. On the day of death this patient was having some difficulty in breathing, respiratory rate was very, very fast, about 60 to 80 per minute. The patient was reported to be cyanotic and also had an irregular rhythm.

One can do a variety of things here.



1
2 We can attribute these symptoms to failure induced
3 or arrhythmia induced by digitalis or you could say
4 that this is something that is attributable to the
5 basic and very severe cardiac disease. I think most
6 people would take the latter position and say this
7 was attributable to the serious disease of the
8 patient. However, in a patient like this presumably
9 no digitalis should be given for this particular problem
10 and here we found in post mortem specimens evidence of
digoxin present.

11 I don't know whether that allows me
12 to conclude frankly that all the symptoms we saw
13 were due to the digoxin, but in the absence of any
14 indication for administration of the drug, I have
15 to put this into the highly suspicious category. I
16 will leave it there with one point that due to the
17 previous comment I have made regarding interpretation
18 of tissue levels, I don't want anyone to infer that
19 these tissue levels were indeed -- or anyone to
20 conclude that the tissue levels infer that digitalis
21 intoxication was present in these patients. I use
22 that post mortem data merely to suggest that it raises
my suspicion that this patient was given digitalis
when it was not officially ordered.

23 Q. In other words, you are
24
25



1
2 considering it to be a qualitative rather than
3 a quantitative analysis of the digoxin that may have
4 been present in the child?

5 A. I think we must, we must,
6 and to give it a little more credence, semi-quantitative
7 might be a better word.

8 Q. Okay. But you cannot infer
9 from those data as to the presence of digoxin in the
10 exhumed tissues what level at all may have been
11 present ante mortem and, therefore, you cannot tell
12 whether it was a toxic level, the fact that it is
13 there at all, coupled with symptoms which could be
14 attributable to digoxin intoxication causing
15 the level of suspicion that you have described.
16 Have I put that fairly?

17 A. That is a correct statement.

18 Q. Okay. And finally we look at
19 Baby Lombardo. Again, I ask you there, Dr. Mirkin,
20 is it anything other than the finding of digoxin in
21 the exhumed tissues of that child for whom the drug
22 had not been prescribed which leads you to the
23 suspicion that digoxin intoxication may have been
24 involved in the death of the child?

25 A. Yes, here is a patient where
we have very scanty data, unfortunately. We had a



1
2 presumptive diagnosis, tetralogy of Fallot, and there
3 was no autopsy performed.

4 THE COMMISSIONER: Did I ever ask
5 for, and if I didn't, could I now ask for an index
6 for Exhibit 95?

7 MR. LAMEK: Exhibit 95 is the -- oh,
8 the Cimbura report?

9 THE COMMISSIONER: The Cimbura report.

10 MR. LAMEK: I don't recall that you
11 did.

12 THE COMMISSIONER: I thought I had.

13 MR. LAMEK: Oh, I am told that you
14 did. Even if you did, you now have, Mr. Commissioner,
15 and one will be provided.

16 THE COMMISSIONER: Good. Thank you.

17 MR. LAMEK: Q. The Lombardo informa-
18 tion is found at page 2 of your report of March
19 25, 1982.

20 THE COMMISSIONER: That's 95-A?

21 MR. LAMEK: No, 95-C, I believe.
22 Yes, 95-C.

23 Q. I am sorry, Doctor, I think
24 I just asked you whether there was anything other than
25 the presence of digoxin in this child for whom it had
not been prescribed that led you to categorize the



1
2 death as you did. You have said that there was
3 rather sparse information and no autopsy.

4 A. Yes. I think that there were
5 some suggested findings. This patient had a cardiac
6 arrhythmia, weak pulse and was vomiting. Now, those
7 might be construed as clinical signs of digitalis
8 intoxication, but we had no electrocardiographic
9 data to go along with that finding. So, we did not
10 make the assumption this was digitalis intoxication
11 until the post mortem data suggested digitalis
12 was there and, like the previous case, I think this
13 would be an assumption based on the presence of the
digitalis in the tissues.

14 Causality is tough or difficult
15 to ascertain here for the same reasons. We don't
16 know what all these measurements mean in this exhumed
tissue.

17 Q. Yes.

18 A. In terms of actual finite
19 amounts of the drug.

20 Q. Do you have before you, Dr.
21 Mirkin, the actual recorded concentrations of digoxin
22 in the exhumed tissue?

23 A. Yes, I have. I have the
24 entire report here.
25



1

2

Q. We have heard evidence, Dr.

3

Mirkin, that although everybody shares your concern about the difficulties of interpretation of tissue concentrations in post mortem samples and

4

5

particularly in exhumed samples, but nevertheless the levels recorded in this child are sufficiently high

6

7

that they can't be totally ignored even in a

8

quantitative sense. Is that a view that you share?

9

A. Well, I think that one doesn't

10

wish to ignore them. It is difficult to attach to them

11

the kind of cause and effect relationship that you

12

desire. For example, can we say merely because this

13

patient's concentration in the left ventricular was

14

487 nanograms per gram that that is going to be

15

considered to be an excessive amount, one capable of

16

causing digitalis intoxication, and I certainly would

17

not want to take that position.

18

19

20

21

22

23

24

25



10jan84
DD
DPrc

1

2

Q. Okay. Understood.

3

4

5

6

7

8

9

10

11

12

13

14

15

16

17

18

19

20

21

22

23

24

25

The symptoms to which you have referred in the course of this child's terminal episode, are set out at page 41 of the chart, which is Exhibit 78, and they include, in addition to those that you have mentioned, those that I heard you mention, in any event a notation that the child, at the time of arrest, was in fibrillation.

A. Yes.

Q. Is that a symptom that you regard as being of any significance in assessing the likelihood of digoxin intoxication?

A. Well, it is a little difficult. I think--certainly, ventricular fibrillation can be associated with an overdose of digitalis, unquestionably. I think that there were a couple of softer signs; the arrhythmias, the vomiting, weak pulse perhaps, suggesting a diminished effect force of contraction of the heart. Those could be taken by many as being clinical signs of intoxication.

So, I think, yes, there are some clinical findings consistent with that. I think the presence of the digitalis in the tissues certainly leaves the possibility open that the toxic effects of the drug were responsible for this patient's death.



DD2

1

2

3

4

5

6

7

8

9

10

11

12

13

14

15

16

17

18

19

20

21

22

23

24

25

Q. Doctor, we have now discussed quite briefly, but nevertheless discussed, each of the children whom you named this morning as either exciting a measure of suspicion or causing you to believe that digoxin intoxication was probably the cause of the child's death.

Were there any other of the 36 children in whom you formed any opinion as to the likelihood or the possibility of digoxin involvement in their deaths? I think particularly of the children whose names you asterisked in your report as having suffered deaths which your team considered to be unexpected and, therefore, you told me this morning, calling for some kind of explanation.

Were you able, in the case of, for example, Adamo, to come to any view as to the possibility that digoxin may have been responsible for that unexpected death?

A. I think we touched on that one. To reiterate, the conclusion we reached was that Adamo suffered the heart arrest following instrumentation with a nasal gastric tube, I believe, and I would say that the likelihood of digitalis intoxication there is very slim.

Q. What about D^r Arcey MacDonald,



DD3

1

2

3

4

5

6

7

8

9

10

11

12

13

14

15

16

17

18

19

20

21

22

23

24

25

your Code No. 60, and also considered by you and your team to be an unexpected death? Is there any basis there, in your view, for considering that digoxin intoxication may have been involved in that child's death?

A. No. In looking through this patient, who had an atrial septic defect and a ventricular septic defect, this patient had no digitalis recorded and was on a dose, when it was being administered, that was considered to be normal or low for that type of patient. We had no evidence of digitalis intoxication at any time. We believed that this patient died following a suction, was being aspirated and had a heart arrest, which would be consistent with the previous patient.

Q. Almost an instrumentation death?

A. Exactly. If you ask if that is unusual, we felt it was probably somewhat unusual to see that but, of course, these things can occur.

Q. What of Frank Fazio, also considered by you to be an unexpected death? Do you have any view as to the possibility that digoxin may have been involved there?

A. This patient also presented



DD4 1
2 a bit of a conondrum. This patient had a coarctation
3 of the aorta, which normally might not be considered
4 anything terrible. We felt that this patient was
5 being treated adequately with the digitalis. The
6 blood levels reported were 1.6 and 1.5 and the
7 death was sudden and unexpected. The patient
8 developed ventricular fibrillation.

9 I put down in my note here that
10 it is a possible unexpected death. We really did not
11 know how to explain that particular patient.

12 So, again, I have no evidence to
13 support the view that the digitalis was involved.

14 Q. When you say "no evidence",
15 do you mean no toxicological or pharmacological
16 evidence to support that view?

17 A. Or clinical evidence.

18 Q. Or clinical evidence, not-
19 withstanding the presence of fibrillation?

20 A. Yes. We cannot use
21 ventricular fibrillation in the terminal period --

22 Q. Per se?

23 A. Yes, exactly. -- as an
24 immutable index of dig. intoxication. We had better
25 not, I would say.

Q. It may, if you had some



DD5

1

2

3

4

5

6

7

8

9

10

11

12

13

14

15

16

17

18

19

20

21

22

23

24

25

other data to suggest the possible involvement of digoxin, such as measurements of digoxin?

A. Yes, or even some signs perhaps, softer signs of vomiting, arrhythmias; things of that sort. One might be led to that type of conclusion.

THE COMMISSIONER: There were no such signs with Fazio; is that correct?

THE WITNESS: To the best of my knowledge, our summary of the chart did not reveal that. In fact, on the day prior to the patient's death, the patient was reported as being improved. There is here a report of bradycardia, slowing of the heart; so one might interpret that as being a digitalis effect but that is about as far as I think we can go with the clinical status, Mr. Grange.

MR. LAMEK: Q. On page 3 of your memorandum report, Dr. Mirkin - I am not sure whether you made him an added starter on the unexpected death stakes this morning, Velasquez, is there any reason to think that digoxin intoxication may have played a part in that child's death?

A. I don't think so. We have nothing in my notes to indicate as much.

THE COMMISSIONER: I wonder if we



DD6

1

2

could put the question another way, doctor.

3

4

5

6

7

8

9

10

11

12

13

14

15

16

17

18

19

20

21

22

23

24

25

Is there any reason to think it may not? I don't say that you should use any assumption one way or the other but it does not help us if you say that it does not, if it is consistent with it, nor does it help us to say that there is no reason to believe that it died of the symptoms from which it was suffering.

You can say anything, but I have tried to tell you before that I am faced with this problem - if the child could have died from one or the other, ordinarily, we don't think of digoxin intoxication in the death of a child because most children don't die of digoxin intoxication. Unfortunately, this has happened in this instance and, therefore, we have to deal with all of these other children. They all became suspicious because of one or two or three or four that were more suspicious and had toxicology to support that. So that is why, when you say there is no reason to suspect that the child died of digoxin poisoning, I would also like to know whether there is any reason to say that he did not.

THE WITNESS: As I understand the evidence, and the way I reach a conclusion -- well,



DD7

1

2

forget about evidence for a minute --

3

4

THE COMMISSIONER: No. If you
are thinking this is a criminal trial, it is not.

5

THE WITNESS: Okay.

6

7

8

9

10

11

THE COMMISSIONER: We are not
faced with -- we don't have to prove cause of death
beyond a reasonable doubt. All I am trying to do
is find out what the cause of death of these children
was. If it develops that Velasquez, that is the
baby from St. Lucia that died, according to some,
of naloxone poisoning - what do you think of that?

12

13

14

THE WITNESS: If that baby died
of naloxone poisoning, I certainly would be very
surprised.

15

16

17

THE COMMISSIONER: I think you
may have told us something.

18

19

20

THE WITNESS: It might be the
first reported case.

21

22

THE COMMISSIONER: I sort of got
that impression also, but it seemed to be the only
explanation that was available.

23

24

25

THE WITNESS: May I make a comment,
Mr. Commissioner?

THE COMMISSIONER: You say he had
a fever and you think he was infected. That is what



DD8

1

2

you said before?

3

4

THE WITNESS: It is certainly a
very leading candidate for the demise of this patient.

5

6

7

8

What I do not understand from
your comments to me, if we have excluded, by dint
of analysis of all the data, all the information,
the possibility that this patient did not die from
digitalis intoxication --

9

10

THE COMMISSIONER: There are too
many negatives in that sentence. Try again.

11

12

13

14

THE WITNESS: Okay.
If we eliminate the possibility
that digitalis was involved in the death of this
patient --

15

16

THE COMMISSIONER: I would be
delighted if you could do that. If you could do that
for me, I would be very grateful.

17

18

19

20

21

Can you do that for me?

THE WITNESS: Again, it is a
question of probability and one can say, based on
this, that there is no evidence that I can see that
digitalis was involved in the death of this patient.

22

23

THE COMMISSIONER: That is one way
of putting it.

24

25

THE WITNESS: That is the only way



DD9

1

2

I can put it.

3

4

THE COMMISSIONER: You can also
put it the other way. This is what is worrying me.

5

6

7

Can you say that there is evidence
that digoxin was not the cause of the death of this
child? Can you say that and, if so, just tell me
what it is.

8

9

10

11

12

13

The only way that you can assist
us - there is no pathology, no possibility of getting
any reading at this point that means anything to us
at all, because the child was apparently on digoxin
and, therefore, the fact there was digoxin in its
tissues would not mean anything.

14

15

16

The heavy readings of Cook,
Miller and Inwood is indicative of something. It
is probably indicative of digoxin poisoning in
one sense or may be explained by something else.

17

18

19

20

21

22

23

The evidence on Lombardo, Hines
and Belanger of there being digoxin at all is
different, because there should not have been any.
But without those, would you be saying the same
thing about Belanger if no one had bothered to
exhume? Would you be saying the same thing about
Belanger and Lombardo; that there is no evidence
of digoxin poisoning?

24

25

THE WITNESS: I think I appreciate



DD10

1

2

3

4

5

6

7

8

9

10

11

12

13

14

15

16

17

18

19

20

21

22

23

24

25

your dilemma but you must understand that one cannot give an assessment of this because of the ambiguity and overlap of the symptomatology, since it can be produced by a variety of causes.

THE COMMISSIONER: Oh, I understand that.

THE WITNESS: Okay. I am sure you understand that very clearly.

Now, if I am able to say that digitalis was minimally involved here - I think we can say that --

THE COMMISSIONER: I don't know if you really need to say "minimally involved" --

THE WITNESS: Or not involved --

THE COMMISSIONER: If you can say it was - and you have told me you can - what I am now asking you is: Can you say it was not?

THE WITNESS: M . . . That means a categorical elimination of that possibility.

THE COMMISSIONER: But even if you can give us a balance, it would be helpful - more likely or less likely, on the basis of your clinical examination of the charts.

THE WITNESS: I think I can say that here but, to some extent --



DD11

1

2

3

4

5

6

7

8

9

10

11

12

13

14

15

16

17

18

19

20

21

22

23

24

25

THE COMMISSIONER: What can you

say here?

THE WITNESS: I can say here that
this patient did not appear to die from digitalis.

THE COMMISSIONER: Why do you
say that?

THE WITNESS: I will say that.
I think that we have, concurrent with the illness
in this patient, fever, which was continuing, as far
as I can surmise, up until the time of death, and
there are notes to rule out the possibility of
systemic infection.



1

2

A. Correct.

3

Q. Did I not refer you to the

4

chart this morning which suggested on the day of
death the child was afebrile and the heart rate went
back to normal 130-140, do you recall I pointed
to that this morning?

5

6

7

A. Wait until I get the last
case again, let me look at this.

8

9

Q. Remember we had trouble finding
all those zeros and the five and the note of the
resident who in fact administered the naloxone?

10

11

A. Yes.

12

MR. OLAH: Page 0004.

13

THE COMMISSIONER: The first one.

14

MR. LAMEK: You missed a zero, Mr.

15

Olah.

16

THE WITNESS: I recall that.

17

Q. Five zeros and a four, for the
first time that combination of digits appears.

18

A. Yes, we made that. Yes, okay,

19

I recall now.

20

Q. This is the resident's note.

21

A. Yes.

22

Q. Last observed at 1 a.m. on

23

August 24th:

24

25

EE
PS



1
2 "Breathing easily, was afebrile and
3 a heart rate of 130 to 140 per
4 hour..."

5 Per minute, I take it to mean:

6 "...according to monitor."

7 We all have problems with units of time.

8 A. No, I recall that quite well
9 now. I guess I can't answer your request,
10 unfortunately.

11 Q. Doctor, may I ask you to consider
12 this and it is a follow up of what the commissioner
13 was asking you. Could you turn to the next page in
14 that note by the resident, five zeros and a five,
15 can we just read through that long paragraph of the
16 note:

17 "At about 3 a.m. on August 24 I was
18 called to see Antonio because of
19 bradycardia less than 90 a minute.
20 When I arrived at the bedside Antonio
21 was somnolent and difficult to arouse.
22 Peripheral pulses were easily felt
23 except in the right arm due to the
24 shunt. Blood pressure in the left arm
25 was 90 over pulse, temperature was
35.3. The pupils were constricted,



1
2 abdomen was soft, liver edge was sharp,
3 no more than 2 centimeters below the
4 right costal margin. Because of the
5 papillary finding, bradycardia
6 and slow respirations, I felt the
7 child had had too much codeine and
8 asked for .4 milligrams naloxone
to be drawn up."

9 Can we pause there. Is that a diagnosis with which
10 you would be able to agree on the basis of those
11 findings, Doctor, that the child was suffering the
12 effects of too much codeine?

13 A. I can say one thing, it certainly
14 is not consistent with digitalis intoxication.

15 Q. What about that constellation
16 of symptoms is inconsistent with digitalis intoxica-
tion?

17 A. I think so.

18 Q. What about it, though?

19 A. Generally speaking, one would
20 expect the patient with digitalis intoxication
21 probably to be presenting more findings of congestive
22 heart failure, so that the liver edge was sharp no
23 more than 2 centimeters below the right costal
24 margin. I would have expected that a patient
25



1

2

who was having failure the liver would be down,
would be more enlarged so that it might be down
4 centimeters.

3

4

5

Q. Even after an acute dose of
digoxin?

6

7

A. No, I think you have to -- oh,
yes, I think I would say that particularly if you are
going to have, if you are going to say there were
effects being produced by the digoxin at this time.

8

9

10

Q. Yes.

11

12

A. Let us say, let us use the
scenario that digoxin was given instead of codeine,
for example, as an example.

13

14

Q. Yes.

15

THE COMMISSIONER: Or in addition to
codeine.

16

17

THE WITNESS: Or in addition to codeine.
Now, one would have expected at least some arrhythmias
and it is true I think here that this patient's heart
rate had slowed.

18

19

20

Q. Yes.

21

A. Which at that point might be
consistent with digitalis, that would also conceivably
be consistent perhaps with codeine.

22

23

Q. Yes.

24

25



1
2 A. The patient was somnolent
3 and difficult to arouse, which would be more
4 consistent with the codeine with a central nervous
5 system depressant than it would be with digitalis,
6 unless the amount of digitalis given had so compro-
7 mised the circulatory system that this patient was
8 in shock. Does that follow now so far?

9 Q. Is that consistent with
10 blood pressure being 90 over pulse in the left arm?

11 A. No, that is not shock so that
12 it's inconsistent with the digitalis being responsible
13 for the somnolence and the lack of arousal.
14 Also the peripheral pulses were easily felt and I
15 would have assumed that the patient was in shock
16 or was having some arrhythmias. Perhaps they might
17 have felt an irregular pulse and that is not always
18 easy to find. A pulse rate of 90 in a patient this
19 age is slow.

20 The pupils were constricted, that
21 would go along more with a narcotic than with
22 digitalis, although at very high doses it is
23 possible to produce an effect on the pupils due
24 to the central nervous system stimulant.

25 I think what we have here would be
more compatible, let us say, with an analgesic effect,



1
2 that is, the codeine exerting some effect on
3 respiration rather than digitalis.

4 Q. I am sorry.

5 A. Excuse me, go ahead.

6 Q. We have looked at the symptoms
7 that Dr. Wilkinson saw when he arrived in the room;
8 and of those, as I understand you, only one, the
9 bradycardia, you would associate possibly with
10 digoxin intoxication, unless the child were in
11 shock in which case the somnolence might also be
12 consistent, but there is no evidence of shock, indeed
13 the evidence is to the contrary with a 90 over pulse
14 blood pressure. So you say the package of symptoms
15 is not indicative to your mind, are not consistent
16 as a whole with digoxin intoxication, but it is
17 more consistent with analgesic effect.

18 Okay, that is suggesting there is
19 no evidence of digoxin intoxication. Can we go
20 to the step the Commissioner wanted.

21 Let's go on with the paragraph:

22 "A new IV had to be started and
23 this was done in the right temporal
24 scalp vein. The IV solution was
25 connected and .2 milligrams of
naloxone was given IV, 5 cc into the



1
2 tubing. Within five minutes the
3 heart rate increased to 140 per
4 minute, pupils dilated to
5 2 to 3 millimetres and were respond-
6 ing more briskly to light. Antonio's
7 activity increased but he did not become
8 fully awake."

Let's stop there.

9 Are you able to express an opinion
10 as to whether that response to naloxone is consistent
11 with this child suffering from digoxin intoxication
12 at that time?

13 A. No, I think it suggests
14 that the effect was more likely due to the codeine,
15 less likely due to the digoxin, or probably not due
16 to the digoxin at all. You see, the reversal of this
17 effect by naloxone suggests that digoxin was not
involved.

18 Q. Are you suggesting, Dr. Mirkin,
19 that had this child been suffering from digoxin
20 toxicity, the effects of the manifestation in that
21 toxicity would likely not have been reversed by
22 the administration of naloxone?

23 A. Yes.

24 THE COMMISSIONER: If the effect
25



1
2 of the codeine and not the digoxin at all, if there
3 had been both codeine and digoxin administered, will
4 the naloxone effect the codeine to give this effect
5 and still the child could have been overdosed with
6 digoxin, is that possible; if it isn't you can
7 help me.

8 THE WITNESS: I would say it is
9 unlikely and next to impossible.

10 THE COMMISSIONER: Tell me why,
11 why is it impossible?

12 THE WITNESS: Because we have no
13 real evidence that digoxin was present in any of the--
14 for many of the findings preceding this event.

15 THE COMMISSIONER: I'm sorry,
16 that is not what I asked you at all. I asked you
17 if the child had been dosed, had been given the
18 appropriate amount of codeine, whatever amount was
19 given, and had also been given an acute overdose of
20 digoxin, would the application of the naloxone
21 have had the effect that it says here upon the
22 codeine that is recorded here, would it have had
23 that effect, or would the fact that the child was
24 suffering from digoxin poisoning, would that have
25 prevented it from having that effect on the
codeine. Maybe that is an impossible question.



1

2

THE WITNESS: It is not an impossible question, it is just not consistent with the facts.

4

THE COMMISSIONER: Well, that is what I am asking you, tell me why it isn't.

5

6

THE WITNESS: Well, I think the answer to your first question, my opinion would be that given the naloxone in the presence of the codeine and the potential presence of digoxin.

7

8

9

Q. Yes.

10

11

12

13

14

A. That the increase in blood pressure, the dilatation, the expansion of the pupils, these all would have occurred in the presence of both digoxin and codeine when the naloxone was administered.

15

16

THE COMMISSIONER: That is all you say would have occurred, is that what you are saying?

17

18

19

20

THE WITNESS: No, that is all we have here, an increase in heart rate; we have the dilatation of the pupils. I am just going to respond to the observations that are reported.

21

22

THE COMMISSIONER: Yes.

THE WITNESS: You know they may have been wrong, I wouldn't know.

23

24

25

THE COMMISSIONER: You say



1

2

it wouldn't have that effect?

3

4

THE WITNESS: Yes, I think I
would anticipate this response in the presence --

5

6

THE COMMISSIONER: Of both codeine
and digoxin?

7

8

THE WITNESS: Yes. Now, let's go
on.

9

10

11

12

13

14

THE COMMISSIONER: All right.

THE WITNESS: Carry this one step
further. Now, to my thinking I have not been able
to provide you with any evidence, I don't think I
have made the statement that digoxin administration
occurred in this baby at any time based on the data
presented in this paragraph.

15

16

17

18

19

20

THE COMMISSIONER: That may well be,
that is another question.

21

22

23

24

25

THE WITNESS: Now that --

THE COMMISSIONER: All I was asking
is can you rule out digoxin, I think that is what
Mr. Lamek is getting at because of the reaction of
the naloxone to the codeine?

THE WITNESS: No.

THE COMMISSIONER: You can't?

THE WITNESS: You shouldn't want
to because -- you can't because it is acting directly --



1

2

THE COMMISSIONER: On the codeine?

3

4

THE WITNESS: Presumably as
directly as drugs act.

5

6

7

8

THE COMMISSIONER: That is what it
is supposed to do, and act on the codeine, and the
fact that the child had been overdosed, if this
was so, with digoxin would it not effect, or would
it --

9

10

THE WITNESS: Unless, it could, you
see, you are attempting to --

11

12

13

14

15

16

17

18

19

20

21

22

23

24

25

THE COMMISSIONER: I am not attempting
anything except to get an answer from you, that is
really what I am after. I'm not trying to prove a
case, I am paid to be neutral on this thing and I am
trying to be that. I want to be able to -- if you can
rule out digoxin poisoning by some process of thought
that I can follow, I would be most grateful. Now,
if you could do it. I thought you were going to do
it by saying that the naloxone would not have that
effect upon the codeine if the child had been over-
dosed with digoxin, but you are now, I think you have
said, no, that is not the reason. The reason is that
you don't see the effects of digoxin in his symptoms
before that, is that right, is that what you are
telling me?



1

2

3

THE WITNESS: No, I'm not telling
you that at all.

4

5

THE COMMISSIONER: All right, what are
you telling me then?

6

7

8

9

THE WITNESS: I am telling you this,
that the naloxone, as you asked me; your question
as I understood it was would naloxone produce its
effect in antagonizing codeine if a dose of digoxin
had been given concurrently.

10

11

THE COMMISSIONER: Not necessarily
concurrently but at the same time.

12

13

THE WITNESS: Concurrently, at the
same time, as I understand the language means that.

14

15

THE COMMISSIONER: I know, but not
necessarily concurrent.

16

17

18

THE WITNESS: Okay, present. We won't
quibble about that. Okay. Now, my response was that
the naloxone will reverse the effects of the codeine
under those conditions.

19

20

21

22

23

24

25

THE COMMISSIONER: Yes, all right.

THE WITNESS: You asked further does
this presence of digoxin in any way modify the response
or would it be anticipated to modify the response
of the codeine to the naloxone. You didn't say that
exactly, but I think that was the inference. I want



1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25

to answer that. If a patient had received a large
enough dose of digoxin, a large enough dose, suf-
ficient to have caused symptoms we would have seen
recorded, then, only then might some modification
of the effect of naloxone on reversal of codeine
effects occur.



1

FF: 2

BM:

yk 3

4

5

6

7

8

9

10

11

12

13

14

15

16

17

18

19

20

21

22

23

24

25

Now, follow the logic if I am clear.

The presumption on my part that digoxin was not administered concurrently or at some time around when codeine was given is based on the fact that there were no symptoms compatible in my mind with the presence of digoxin during this time period, i.e., I conclude no digoxin was given during that time.

THE COMMISSIONER: All right. Well then, let me just see.

THE WITNESS: All right. Now, is that clear, please?

THE COMMISSIONER: Yes, that is clear to that point.

THE WITNESS: All right.

THE COMMISSIONER: Now, the terminal events of this child, that is, not at the time but when the second naloxone was given in the IV tubing, et cetera, promptly had an extensor posturing and the loss of detectable cardiac electro-mechanical activity, et cetera, and there are several more nurses' notes and various assorted other things that we can find here. I don't know whether you have studied those. Are those compatible with digoxin poisoning?

THE WITNESS: May I make just a comment



1
2 on it. I am going to say no and I will explain why.

3 THE COMMISSIONER: Okay.

4 THE WITNESS: The development of
5 extensor posturing is like that, and that would be
6 attributable primarily to some effect on the central
7 nervous system, perhaps a seizure activity more
8 or less. It is when someone gets electrocuted if
9 you don't strap their arms you will see it. Of
10 course, you are all against criminal ... Well.
11 The point is that that is one observation I think
12 that mitigates against this being a digoxin overdose.
13 I think this presence of seizure activity, and I
14 would, you know, in a qualifying statement, while
15 seizures have been observed and reported in the
16 literature in patients receiving overdoses, I tend
17 to minimize it.

18 THE COMMISSIONER: Yes, it is not
19 usual but it does happen, we have had that earlier.

20 THE WITNESS: Yes, I am sure you
21 have had that presented and if you look in the
22 text book it is there.

23 THE COMMISSIONER: Is there anything
24 else?

25 THE WITNESS: Now, the second part,
the loss of detectable cardiac electro-mechanical



1
2 activity. Essentially they are saying that the
3 heart came to a complete stop, bingo, and that's
4 what they are saying as I read that, and that means
5 the electrocardiogram became flat.

6 Well, I would submit to you that
7 if we gave a very large dose of potassium we would
8 get a very flat iso-electric cardium, just like that.
9 I don't think that that categorically eliminates
10 the possibility of digoxin overdose but I certainly
11 wouldn't have expected it to manifest itself so
12 rapidly and for that reason I guess I am minimizing
13 the likelihood of digitalis in the situation.

14 THE COMMISSIONER: Yes, all right.
15 Well then, I think we will take 15 minutes.

16 MR. LAMEK: 15 minutes, thank you,
17 sir.

18 --- Short Recess.

19 --- Upon Resuming.

20 THE COMMISSIONER: Yes, Mr. Lamkek.

21 MR. LAMEK: Q. You may have thought,
22 Dr. Mirkin, that Velasquez was all hashed out but
23 no such luck, not quite. Could we go back to the
24 chart and to the page at which we were looking,
25 which was the 000005 for the first time they appear
in the chart.



1
2 Just let me follow up and understand
3 very clearly if I can the response to the questions
4 that the Commissioner was asking you. For the
5 purpose of these questions let us assume that in
6 addition to the prescribed dose of codeine there had
7 also been administered an unprescribed and large
8 dose of digoxin to this child. Can we assume that?
9 Let's see what would happen if that were the background
10 against which we were working.

11 We have the administration of .4
12 milligrams of naloxone in the face of the set of
13 symptoms that are recorded in this page. Now, that
14 set of symptoms you have said that the only one
15 which in your view is consistent with any indication
16 of digoxin toxicity is the bradycardia. Do I have
17 that correctly?

18 A. That is correct.

19 Q. Okay. Now, the bradycardia
20 is affected by the first administration of naloxone
21 and the heart rate goes from less than 90 per minute
22 to 130 to 140?

23 A. Correct.

24 Q. To 140 per minute, a sub-
25 stantial increase in the heart rate. Had the brady-
cardia, which is noted at the top of that page been



1

2

a manifestation ---

3

THE COMMISSIONER: I'm sorry,

4

bradycardia, is it?

5

MR. LAMEK: Bradycardia, yes.

6

Q. Had the bradycardia down to

below 90 per minute ---

7

THE COMMISSIONER: Where is that?

8

MR. LAMEK: The top line of the page,

9

Mr. Commissioner, bradycardia less than 90 per minute.

10

THE COMMISSIONER: Oh, yes, yes,

11

thank you.

12

MR. LAMEK: Q. Had that bradycardia

13

been a manifestation of the digoxin effect or a

14

combination of the digoxin and codeine effect if

15

digoxin had played any part in producing that brady-

16

cardia, would it have increased to the rate that it

17

did upon the administration of .4 milligrams of

naloxone in your best judgment?

18

A. No.

19

Q. All right. So, may I take it --

20

THE COMMISSIONER: Could you just

tell me, where is the part about -- blood pressure ---

21

MR. LAMEK: No, 2, 4, 6, 8, 9 lines

22

from the bottom there is a sentence:

23

"Within five minutes the heart rate

24

25



1

2

"increased to 140 per minute."

3

THE COMMISSIONER: Yes, all right.

4

MR. LAMEK: Q. Now, do I take it
from that answer, Dr. Mirkin, that in your judgment
the increase in the heart rate following the first
administration of naloxone -- I'm sorry, .2 milligrams
of naloxone, the increase in heart rate following
that first administration suggests that whatever
was causing the bradycardia that was noted earlier
it probably was not digoxin?

11

A. That's a reasonable conclusion.

12

13

14

15

16

Q. All right. Now, that still
doesn't preclude the possibility that digoxin had
been administered, it merely suggests that there
were at that stage no symptoms resulting from the
administration of digoxin, is that fair, or no
observed and recorded symptoms?

17

18

A. Well, it is a question if it
is correct.

19

20

21

22

23

24

25

Q. Well, I mean, can you see
any other recorded symptoms. You have told me the
only one was badycardia which you have now ruled out
because you said you wouldn't think that would have
been changed by the administration of naloxone if
digoxin caused.



1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25

A. Now, can I respond, Mr.
Lamek?

Q. Yes, sure.

A. Thank you.

Q. I am not sure what you're
responding to but go ahead anyway.

A. If the digoxin was given,
the large overdose we are saying.

Q. The assumption?

A. The assumption, yes.

Q. Yes.

A. One of the points, pieces of
information that, and we may have it here, is the
time frame over which these events occurred.

Q. Yes.

A. Now, if one were to give a
large overdose of digoxin intravenously, or even
a small overdose, let us say, one would have anticipated
that some of the effects would be manifest during
what I think is the time frame over which these events
occurred. Now, at 3 a.m. the doctor was called. I
do not have a clear statement on when the second dose
of naloxone was given, perhaps it is in my record.

Q. Well, the only temporal
relationship I see is in the paragraph itself that he



1
2 observed certain response within five minutes, didn't
3 think it was enough so gave more naloxone. I think
4 reasonable to infer from that that it was 5, 6, 7
5 minutes later.

6 A. Well, I have in my notes here
7 six hours after the last codeine dose the patient
8 developed bradycardia and miosis. This is six hours
9 after the last dose.

10 Q. Yes.

11 A. And this was treated with
12 naloxone times two, two doses.

13 Q. Yes.

14 A. And the patient then suffers
15 cardiac arrest. Now, again, going with your scenario,
16 since we must, if the codeine was given six hours
17 prior to the naloxone is it fair for this purpose
18 to assume that perhaps the digoxin was given at that
19 same time or must we assume the digoxin in this
20 scenario was given after the codeine?

21 Q. I make no assumptions to this
22 as to the time of administration of the assumed dose
23 of digoxin.

24 A. Well, if you don't make an
25 assumption let me say that we must because if we
are going to postulate digoxin being present at the



1

2

same time, which is not an unreasonable proposition.

3

Q. Yes.

4

5

6

7

8

Q. Okay. Yes.

9

10

11

12

A. That's the point I am making.
And since there were no effects that I could discern
attributable to the presence of digoxin we must assume
none was given.

13

14

15

16

17

18

19

20

21

22

23

24

25

Q. We may arrive at the same
place at the end of this road.

A. I doubt it.

Q. Well, bear with me, let's
find out.

A. Okay, go on.

Q. As I understand you so far in
the series of questions I have put to you, one has
to assume that the bradycardia which was observed,
the only symptom which you say to have been consistent
with digoxin effect was not attributable to digoxin
because had it been, you told me, you would not
have expected the bradycardia to be reversed as



1

2

dramatically as it was.

3

A. Okay, that's clear.

4

Q. That's clear. Therefore, as

5

at that stage we have no recorded symptoms in this

6

interlude at 3 which are consistent with digoxin
intoxication. Is that also fair?

7

A. Correct.

8

Q. All right. Now, I said to

9

you that however doesn't necessarily preclude the

10

possibility that at some time perhaps shortly prior

11

to 3 o'clock digoxin had been administered but its

12

effects had not yet become manifest, is that also
fair?

13

A. I think one could accept

14

that.

15

Q. Okay. Now, in order for

16

digoxin to have contributed to this child's death,

17

therefore, its effects must have been felt at some

18

time I take it between the response to the naloxone

19

and the administration of the second dose and the

20

immediately ensuing arrest, is that fair?

21

A. Yes, I think that is what

22

we must conclude I would think, yes.

23

Q. All right. Now, the only

24

recorded effect, symptom of this child that follows

25



1

2

that initial response to the initial naloxone is

3

that his heart stops like that, is that fair?

4

A. Yes.

5

Q. There is the extensor

6

posturing as well?

7

A. That's what they say, right.

8

Q. Okay. And we have no other

9

evidence to go on. In your view and in your experience

10

is it - let's start with a probable - that digoxin

11

intoxication would have as its only manifestation

12

extensor posturing, an immediate cessation of all

13

heart activity?

14

15

16

17

18

19

20

21

22

23

24

25



1

10jan84 2

GG

DPrC

3

A. I think that is an unusual presentation of events.

4

Q. Is it possible that that could be the only manifestation of digoxin toxicity?

5

6

7

A. Yes, I think one has to say it is certainly possible.

8

9

10

11

12

13

14

15

16

17

18

19

20

21

22

23

24

25

Q. All right.

Now, I am going to ask you to play a numbers game with me. On a scale of 1 to 10, rate that as a possibility - from remote possibility through to probability, large possibility, small possibility, remote possibility. Can you help me at all.

THE COMMISSIONER: With zero being no chance at all.

MR. LAMEK: Zero being impossible.

A. On my usual 0 to 10?

Q. Yes.

A. I would put this at a 10 per cent possibility.

THE COMMISSIONER: That is about a 1, I guess?

THE WITNESS: Yes, a 1.

MR. LAMEK: Q. Is it, therefore, your opinion, Dr. Mirkin, that the possibility that



GG2 1
2 digoxin played a part in this child's death is
3 exceedingly small?

4 A. Correct.

5 Q. So small as to make you
6 challenge the initial assumption that digoxin was
7 administered at all?

8 A. Assumption by whom?

9 Q. The one that you and I were
10 sharing for the purpose of our discussion.

11 A. I'm sorry, I missed that. I
12 thought that was real fact.

13 Yes, I do challenge that.

14 Q. So, we really did wind up
15 at the same place, you and I?

16 A. Yes, I guess we did.

17 Q. That still leaves us in a
18 terrible quandary as to the cause of this child's
19 death, of course, does it not?

20 In your best judgment, as I
21 understand you, you think it very unlikely that it
22 is attributable to digoxin intoxication?

23 Do I understand you correctly?

24 A. Yes, I must conclude that.

25 THE COMMISSIONER: You said the
fever. Does the fact that he seemed to have recovered



GG3

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25

from his fever, was afebrile, does **that** affect **that**
at all?

THE WITNESS: It is quite clear
that that may not have been as important a fact in
the death as I might have indicated earlier. I cannot
see anything here that would suggest that the
infection was the cause of death, at least in this
note.

I wonder if there was some informa-
tion in the post mortem about the presence of
infection anywhere? Is that in the front of the chart?

MR. LAMEK: I am just looking
for the post mortem report.

MR. OLAH: 000006.

THE COMMISSIONER: The first time
or the second half, is it, Mr. Olah?

MR. LAMEK: I think the second time,
Mr. Commissioner. Page 000002 starts the Coroner's
Act post mortem report and, on 000005, for the
second time, the cause of death is reported by
Dr. Mancer as "undetermined".

On the the Hospital pathology
report form, which is the one we are accustomed to
seeing in these charts, I don't see any reference to
sepsis.



1

GG4

2

3

4

5

6

7

8

9

10

11

12

13

14

15

16

17

18

19

20

21

22

23

24

25

Q. Dr. Mirkin, you said this morning - obviously, I accept this - that the failure to grow any culture even over the space of 21 days is not absolutely definitive as to the absence of any bacterial infection, but does the failure to produce any growth over that period, coupled with the apparent resolution of the fever, suggest that, indeed, sepsis was not the correct diagnosis?

A. I think I would have to minimize sepsus in view of the fact that the chest X-ray was normal. As well, I don't know what that fever was due to, and we can just leave it at that.

Q. Doctor, you will be relieved to know that I have two more children about whom I want to ask you.

Anything else on Velasquez, Mr. Commissioner?

THE COMMISSIONER: No. I am exhausted.

MR. LAMEK: You need some haloxone!

Q. Another child whose death was regarded by you and your team as unexpected was Laura Woodcock.

Can you help me, is there anything in that child's course or history that gives you any



GG5

1

2

3

4

5

6

7

8

9

10

11

12

13

14

15

16

17

18

19

20

21

22

23

24

25

cause to believe that digoxin intoxication may have played a part in her death?

A. Well, here is a patient who really did not seem to have a terribly severe congenital heart defect. It says here, "Jaundice, severe etiology and some valvular defect." Aside from the fact that baby had an enlarged liver and was having feeding difficulties, there was nothing of a cardiovascular consequence to suggest that death was imminent. But this patient, on the 30th of June, after being observed for four days, developed a very irregular heart rate and started vomiting. The vomiting might have been associated with, or secondary to, the jaundice, the liver disease, but three hours after this, developed complete heart block and disassociation of the rhythm, which responded to atropine, increased the heart rate, and three hours after that--in the course of six hours, the baby went from a fairly stable position to cardiac arrest and ventricular fibrillation. The sequence of electrocardiographic abnormalities is very consistent with digitalis presence, despite the fact that we found no record of digitalis being given in this patient. There is none recorded in the chart.



GG6

1

2

3

4

5

6

7

8

9

10

11

12

13

14

15

16

17

18

19

20

21

22

23

24

25

We concluded that we could not find any obvious cause for the very rapid progression of this patient's problems and concluded that this was an unexpected death. I think I would have felt that there was, on a clinical basis now, some reason to think digitalis or a digitalis-like drug was affecting the heart.

Q. An expression that we have heard from time to time in the course of these proceedings, Dr. Mirkin, is "index of suspicion".

Could you give us some indication of the index of suspicion that you have with respect to this child?

A. I would kind of put this up about, on my scale, 7 out of the 10. I think that the clinical pattern is very consistent with a digitalis effect here, so I would make it highly probable that digitalis was exerting this type of an effect.

Q. In a child for whose death there is no ready explanation on the face of the clinical record, I take it?

A. That is right. That was the reason we put this patient in here.

Q. And the last of the children



GG7 1
2 is Real Gosselin. He was regarded by you as having
3 suffered an unexpected death.

4 Is there any reason, in the case
5 of that child, in your opinion, to consider that
6 digoxin intoxication may have been involved in that
7 unexpected death?

8 A. This patient was one that
9 I reviewed and the patient expired after one day in
10 the Hospital. It had had fairly severe congenital
11 disease, consisting of coarctation of the aorta and
12 several other defects and was in a failure; so this
13 patient was feeding poorly and really was not in the
14 best of health, one would say.

15 But the patient was brought in on
16 the 15th of December. On the 17th of December, the
17 patient was brought into Toronto Children's Hospital
18 and was described as "resting comfortably; no
19 cyanosis, a slight murmur", and the liver was very
20 enlarged. "No acute distress" was the description.

21 The digitalis was not administered
22 because, at this time, this patient had a relatively
23 high level for its age, 3.9 nanograms per ml. The
24 patient was treated with some drugs - we do not need
25 to go into detail on this - and suffered from apnea
during this time. That was on the 17th of December,



GG8

1
2 in the morning.

3 In the evening of December 17th,
4 the baby experienced a respiratory arrest, the
5 second episode of apnea that the baby had experienced,
6 and on December 18th, in the morning, the baby had
7 bradycardia, slowing of the heart rate - that
8 resolved spontaneously - and then had a cardiac
9 arrest.

10 We have one elevation, an ante
11 mortem level I believe, that represents a 3.9,
12 consistent with dig. intoxication, and there, of
13 course, some findings in this patient that suggested
14 dig. intoxication as being present at the time of
15 death and perhaps contributory to this patient's
16 demise.

17 The major thing, I think, that
18 we used as a basis for this conclusion was the
19 sudden change in the clinical status of the patient,
20 which we felt supported the diagnosis of intoxication.

21 While I give you the positive
22 findings, it is important to mention that there were
23 two observations that, while consistent with digitalis
24 intoxication, are not always positive proof.

25 One of these -- I talked about the
serum level being 3.9. There are many patients in



GG9

1

2

3

4

5

6

7

8

9

10

11

12

13

14

15

16

17

18

19

20

21

22

23

24

25

whom this does not produce intoxication. The second point is that we assume that the slowing of the heart rate, the bradycardia I mentioned, was attributable to digitalis but slowing of the heart rate could also be attributed to apnea.

So, with that analysis, we concluded that digitalis intoxication was present, and I think we can't say much more than that, and that seemed to be an unexpected death due to the fact that the patient was stable on the day before its death.

Of course, that is a judgment call as to whether that is unexpected.



H-1
/PS

1

2

3

4

5

6

7

8

9

10

11

12

13

14

15

16

17

18

19

20

21

22

23

24

25

A. I think considering the nature of the disease, you know, certainly sudden death can occur in these patients, but at the time I think it was not considered to be a likely probability based on our interpretation of the patient's condition.

Q. Well, were you able to assign a probable cause of death for this child?

A. No, I think we concluded this patient was digitalis intoxicated and that these arrhythmias and the blood bradycardia was attributable to the digitalis.

Q. Is that the intoxication you think to be reflected by the concentration of 3.9?

A. I think that is the only objective data we have. I am trying to see whether we have any EKG data on that, and if you will bear with me for a moment I will look that up.

Q. Yes, of course. According to Dr. Moller's report, the EKG of the 17th of December showed a major ST segment change.

A. Okay.

Q. And PR interval of 1.4 seconds.

A. Okay. Well, this would be



1
2 consistent with the presence of this patient
3 receiving dig.

4 Q. That is dig. effect, is it?

5 A. Yes, exactly, and we -- without
6 knowing the heart rate I wouldn't want to make a
7 comment on whether this interval is prolonged, it
8 is probably on the high side, so we may be seeing
9 more of a digitalis effect and maybe the early signs
10 of intoxication in the EKG.

11 Now, I think we have here then
12 confirmatory evidence of the presence of digitalis
13 in the patient; we have the measurement, we have
14 one clinical finding of bradycardia which is
15 consistent with the first degree heart block, or
16 second degree heart block, and I think that we have
17 enough evidence to suggest digitalis intoxication
18 here.

19 Q. As having contributed in some
20 way to the death?

21 A. Well, since it was present
22 at the terminal portion of this patient's illness,
23 maybe we should, we can't exclude that possibility,
24 I would say.

25 Q. Can you exclude the possibility
of the further administration of digoxin following



1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25

the 3.9 concentration?

A. No, we can't, unless there is data indicating that that did occur somehow, measurements of some sort.

Q. No evidence of it?

A. No.

Q. But I take it there is nothing in the chart that would lead you to say that could not have occurred.

A. Certainly.

Q. Doctor, then, in addition to the children whom you have identified, Miller, Cook, Hines, Belanger, Lombardo, Woodcock, and the possibility of this last child, was there any other of these 36 children of whom you and your team formed the opinion that there was a possibility of digoxin involvement in the death?

A. No. We just made conclusions based on those children that are asterisked.

Q. And certain who were not asterisked as well, such as --

A. Oh, okay, yes.



1

10jan84 2
HH
DMrc 3

THE COMMISSIONER: No, but you
considered though but you decided against it.

4

Is that it, is that what you are
saying?

5

6

THE WITNESS: Yes because we felt
that the death could be explained by other causes.

7

8

THE COMMISSIONER: We have been
through this before and this is where I came in.

9

10

11

12

13

14

15

16

17

18

19

20

MR. LAME: Q. I am reminded
about the child Estrella who had I confess tended
to take rather a backseat in light of the evidence
as to the studies done on samples drawn in a way
similar to that in which the sample was obtained
from that child and recorded at the 72 nanogram
level. Forgive me, I may have asked you this, I
have a recollection of asking something similar.
Was the judgment that you told me about earlier
formed about that child and the likelihood of
digoxin involvement in her death based entirely,
or to any large extent upon that post mortem 72
nanogram concentration?

21

22

23

24

25

A. I think it was based almost
exclusively on the elevated blood level. But also
there were some suggestions of heart block on the
electrocardiograms. So we do have not only AV block,



HH2

1

2

3

4

5

6

7

8

9

10

11

12

13

14

15

16

17

18

19

20

21

22

23

24

25

that term is familiar to everyone by now, right;
this thing called a Wenckebach phenomenon which has
also been explained Mr. Lamek?

Q. A long time ago and we have
all forgotten about it.

A. Wonderful, let's forget
about it again. But suffice it to say that it is
a quite characteristic finding with digitalis where
the magnitude of the dissociation between the
atrium and the ventricle undergoes a change with
time, it gets longer and then it shortens up and
then it gets longer and longer again with each beat,
it is an interesting phenomenon.

THE COMMISSIONER: What is it
called again?

THE WITNESS: Wenckebach.

THE COMMISSIONER: How do you
spell it?

THE WITNESS: W-e-n-c-k-e-b-a-c-h.

THE COMMISSIONER: ... b-a-c-k?

THE WITNESS: The composer of
the same name, bach.

THE COMMISSIONER: Oh yes.

THE WITNESS: I'm glad that has
reached Canada.



HH3

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25

MR. LAMEK: Q. We think it is Welsh
for brother, Dr. Mirkin.

A. Naughty.

Q. Can you remind me, does
your note tell you where the AV block occurred?

A. Yes. We have this data,
these data on 1.7, that is January 7th.

Q. That is the time of the
early elevation of the serum digoxin, four days
prior to death?

A. For some reason the digoxin
levels were not -- oh, here we are, I am sorry I have
the wrong page. Yes we have, the digoxin levels
were up roughly about 5 nanograms per ml.

Q. The evidence has been doctor
those on dilution were approximately 10.

A. 10?

Q. Yes.

A. Okay. So we do have evidence
here that the concentration achieved in this patient
was certainly consistent with the clinical findings
that were presented to you.

Q. Yes.

A. Now whether the 72 is real
or not I still think that there is evidence in
this particular patient, Mr. Lamek, that digitalis



HH4

1

2

3

4

5

6

7

8

9

10

11

12

13

14

15

16

17

18

19

20

21

22

23

24

25

intoxication was present and indeed perhaps may have been contributory to the demise of this patient. Yet I realize that it is -- I didn't asterisk this patient, but on looking it over now I am not sure why this was eliminated from consideration. Because even as late as January 9th, two days before the baby died on the 11th -- yes, two days before we had a serum digoxin, we have about 5. So I think we have data in my opinion that this patient was intoxicated, whether more was given at the time of -- during that period between the 9th and the 11th to account for the elevated -- for the 72, I don't know, the 72 now is in contention, is that correct?

Q. Yes.

A. Yes, so we can just discard that from our thinking.

THE COMMISSIONER: The contention I think mainly because there was some evidence given, it wasn't given initially, about the bowel having been cut and the possibility of contamination from the bowel, the pelvic cavity from which they took it, isn't that right?

MR. LAMEK: Perhaps even more than that, even more graphically Mr. Commissioner the subsequent study that was done disclosed that one



HH5

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25

of a series of 14 such samples could produce a
very high level indeed.

THE COMMISSIONER: Yes.

MR. LAMEK: And one cannot be
sure that this wasn't one of the 14.

THE COMMISSIONER: That is it,
the contamination appeared from somewhere, from the
bowel.



1
2 THE WITNESS: Even if we exclude
3 the relevance of that particular piece of information,
4 this patient has sustained high blood levels and
5 certainly this was, this correlates with the
6 clinical presentation, the electrocardiographic data
7 and must be considered as contributory to the cardiac
8 arrest.

9 Q. Certainly, Doctor, the child
10 had been dig. toxic?

11 A. Yes.

12 Q. And it manifested symptoms
13 of digoxin toxicity as you said heart block and so
14 on at around the 7th of January and the levels were
15 at their peak. The concentrations appeared over
16 the course of the next two or three days to be coming
17 down, from a level of 10 to as I recall it 7 point
18 something down to 4.7, the last recorded level prior
19 to death.

20 A. That is correct.

21 Q. Is there any evidence in the
22 chart that you are aware of of indications of digoxin
23 toxicity at or shortly, immediately before the time
24 of this child's death?

25 A. Well our notes don't describe
any important event occurring up until the 11th of



1
2 January, the time of death when cardiac arrest is
3 described.

4 Q. Yes.

5 A. Now I don't know what happened
6 on 1.10, I would like to look at the chart and
7 examine what was present at 1.10 and 1.9, or 1.10
8 particularly.

9 Q. The note for January 10th,
10 Doctor, I can help you, page 126 for the day
11 beginning 7 a.m. running to 7 p.m.

12 A. Yes.

13 Q. Was:

14 "The apex was regular all day between
15 1:10 and 1:47. Elevated went up -
16 et cetera; respirations remained
17 tachypneic, colour appears to be
18 a better colour today, still pale."

19 Not a horrendous picture?

20 A. You say the heart rate went
21 up, is that correct?

22 A. The heart rate went up when
23 upset or irritable but remained at 1.10 to 1.47
24 and was said to be regular all day.

25 A. So I think one might conclude
that enough digitalis had been removed from the body



1
2 so that at least the rhythm in this patient, the
3 heart rate was in the normal range. Based on that
4 I would have to conclude that the digitalis
5 intoxication was not present at that time. Okay?

6 Q. 1.10 on January the 10th?

7 A. Exactly, at least was not
8 being clinically manifested, the patient seemed
9 normal, stable, what happened at 1.11 I don't know.

10 Q. Of course.

11 A. All I have is cardiac arrest,
12 and I don't think we can make a judgment on it.

13 Q. And the 72 nanogram level,
14 had that been a true bill as they say one might have
15 inferred administration in that period I take it.

16 A. I think one correctly could
17 do that.

18 Q. The question is you cannot
19 with any confidence make that supposition?

20 A. Yes I think we had better
21 not.

22 MR. LAMEK: Dr. Mirkin those are my
23 questions and I think we have more than reached the
24 end of the day, I think others may have questions of
25 you tomorrow.

THE COMMISSIONER: 10 o'clock then.

MR. LAMEK: Thank you, sir.

---Whereupon the hearing adjourned at 4:45 p.m.
until 10 a.m. the 11th day of January, 1984.
